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In The

Supreme Court of the United States

October Term, 1996

ADA M. MARTIN and HAROLD L. MARTIN,

Petitioners,

vs.

TELECTRONICS PACING SYSTEMS, INC.; TPLC, INC. d/b/a Telectronics Pacing Systems; TELECTRONICS PTY LIMITED,

Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Do the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, as interpreted by this Court in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), preempt Petitioners' state law tort claims to recover for injuries caused by a defective medical device?

2. Does preemption of state law tort causes of action under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act violate Petitioners' right to a jury trial under the Seventh Amendment to the United States Constitution?

RULE 29.6 STATEMENT

To the best of the knowledge of counsel for the Petitioners, all parties including all divisions of the corporate Respondents are contained in the caption of the case.

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OPINIONS BELOW

The opinion of the Court of Appeals on remand from this Court is found at 105 F.3d 1090 (6th Cir. 1997) and is reproduced in the appendix to this petition at Pet. App. A at p. 1a. The order allowing certiorari of this Court is found at 116 S. Ct. 2576 (1996) and is reproduced in the appendix. Pet. App. C at p. 25a. The prior opinion of the Court of Appeals is found at 70 F.3d 39 (6th Cir. 1995) and is reproduced in the appendix. Pet. App. D at p. 26a. The memorandum and order and judgment of the United States District Court for the Southern District of Ohio, Eastern Division, granting summary judgment on September 7, 1994, to the Respondents is unreported and is reproduced in the appendix to the petition. Pet. App. E at p. 33a. The Opinion and order of the United States District Court for the Southern District of Ohio, Eastern Division, granting on December 14, 1993, partial summary judgment to the Respondents is unreported and is reproduced in the appendix to the petition. Pet. App. F at p. 42a.

STATEMENT OF JURISDICTION

The Court of Appeals entered judgment on January 31, 1997. This Court has jurisdiction under 28 U.S.C. § 1254(1).

Rule 29.4(b) Statement

The constitutionality of an Act of Congress is drawn into question. Accordingly, 28 U.S.C. § 2403(a) may apply. The United States Court of Appeals for the Sixth Circuit and the United States District Court for the Southern District of Ohio, Eastern Division, did not certify to the Attorney General pursuant to 28 U.S.C. § 2403(a) the fact that the constitutionality of an Act of Congress was drawn into question. Three copies of this petition were served by Lutz Appellate Services, Inc. on the

Solicitor General of the United States at Room 5614, Department of Justice, 10th Street and Constitution Avenue, N.W., Washington, D.C. 20530, at the time of its filing with the clerk of this Court.

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

The principal constitutional provisions, statutes and regulations involved in this case are as follows: Article VI and Amendments VII, IX, and X to the United States Constitution; 21 U.S.C. §§ 360j(g), 360k, and 360h(d); 21 C.F.R. § 808.1(d); and Ohio Revised Code §§ 2307.71-.80. These provisions are reproduced in the appendix to this petition. Pet. App. G at pp. 54a-87a.

STATEMENT OF THE CASE

A. Facts and Lower Court Proceedings.

On March 31, 1992, doctors surgically implanted in Petitioner, Ada Martin, a Guardian 4210 Cardioveter/ Defibrillator System manufactured and/or supplied by Respondent Telectronics. This system was composed of four component parts: Model 4210 defibrillator, Model 040-106 leads, Model 033-572 leads, and Model 033-415 Y-adapter. A defibrillator functions by detecting abnormal heart rhythms and by generating an electrical shock to the heart muscle. The shock acts to terminate the detected arrhythmia and to restore a rhythm of heart contractions which conforms to that programmed within the defibrillator. The device at issue functions with a design which provides combined functions of a defibrillator with a cardioveter and a pacemaker.

The Guardian 4210 System, including all four component

parts, is a medical device currently subject to investigational testing pursuant to the Medical Device Amendments to the 1938 Food, Drug and Cosmetic Act ("MDA") and pursuant to regulations promulgated under MDA by the United States Food and Drug Administration ("FDA"). At all times relevant to this case, the product system had secured "investigational device exemption" ("IDE") under MDA. (R. 43, Exhibits A-3, A-4, A-5 to Defendants' Motion for Partial Summary Judgement). However, it is important to note that two of the four components of the 4210 system, the Model 033-572 leads and the Model 033-415 Y-Adapter, were used in the system under a Section 510(k) exemption and not through the IDE exemption. The Model 033-572 leads were granted a Section 510(k) exemption by letter dated July 14, 1989; the Guardian 4210 system was granted an IDE exemption by letter dated July 19, 1990; and the Model 033-415 Y-Adapter was granted a Section 510(k) exemption by letter dated April 1, 1991. (R. 43, Exhibits A, B and C to Defendants' Motion for Partial Summary Judgment). Also, the Model 033-572 leads and the Model 033-417 Y-Adapter were not listed in the consent form executed by Mrs. Martin (R. 43, Exhibit A-6 to Defendants' Motion for Partial Summary Judgment).

Mrs. Martin alleged that her implanted Guardian 4210 System began to malfunction subsequent to March 31, 1992, which required surgical replacement of the system on November 19, 1992. Charles J. Love, M.D., one of Mrs. Martin's treating physicians, indicated his belief that the Y-Adapter was the malfunctioning component of the 4210 system (Dr. Love deposition, pp. 38-40, R. between R. 28 and R. 29). As a result of the malfunction, Mrs. Martin claims that she suffered trauma to her body structure, permanent physical pain, anxiety, mental distress, loss of enjoyment of life, inability to perform ordinary activities, and physical impairment. She also claims that she will incur medical expenses in the future and lost income in the

future. Her husband claims derivatively that he has lost services, companionship, and consortium now and in the future. They claim damages in the amount of $500,000, together with interest and costs.

Petitioners, Ada and Harold Martin, initiated this action on May 14, 1993, in the Common Pleas Court of Franklin County, Ohio. The Respondents, Teletronics, Inc., *et al.*, filed their notice of removal on June 10, 1993, and the Petitioners thereafter filed a motion to remand which was overruled by the District Court. Both parties moved for partial summary judgment, and by way of opinion and order filed on December 14, 1993, (Pet. App. C at pp. 17a-28a), the District Court granted Respondents' motion and overruled the Petitioners' motion. On February 23, 1994, the District Court issued an order permitting the Petitioners to file an amended complaint. The amended complaint asserted the same claims for relief as the original complaint, but also added claims relating to additional components of the Guardian 4210 System. Thereafter, the parties filed cross-motions for summary judgment. Respondents asserted that the Petitioners' Ohio statutory and common law claims for damages based upon product liability and loss of consortium were preempted by 21 U.S.C. § 360k(a). The Petitioners asserted that their state law claims were not preempted because of the language contained in 21 U.S.C. § 360h(d) and 21 C.F.R. § 808.1(d), and also, that if their claims were preempted, such preemption by Congress would violate the Seventh Amendment to the United States Constitution. The District Court issued its decision and judgment on September 7, 1994 (Pet. App. E at p. 33a), granting Respondents' April 29, 1994, motion for summary judgment, dismissing the complaint of the Petitioners and entering judgment in favor of Respondents. The District Court's decision was based upon a finding of federal preemption of state tort law. The court did not address the issue of whether or not failure of Congress to provide for a tort remedy violates the Seventh

Amendment to the United States Constitution. The Petitioners filed their notice of appeal in the District Court on September 20, 1994, and the Petitioners timely filed their brief in the Sixth Circuit United States Court of Appeals on November 7, 1994. That Court issued its decision affirming the District Court on November 20, 1995. A petition for writ of certiorari was timely filed in this Court, and on July 1, 1996, this Court granted the petition and remanded this cause to the Sixth Circuit Court of Appeals for further consideration in light of *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). After further briefing by the parties and oral argument, the Sixth Circuit issued its decision again affirming the District Court on January 31, 1997, *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997). (Pet. App. A at p. 1a).

B. Jurisdiction in the Lower Courts.

The jurisdiction of the United States District Court for the Southern District of Ohio, Eastern Division, was based upon diversity jurisdiction as set forth in 28 U.S.C. § 1332. The Petitioners are residents of the Souther District of Ohio. The Respondents are business entities having their principal place of business in the State of Colorado, and the amount in controversy exceeded $50,000. The District Court also had federal question jurisdiction under 28 U.S.C. § 1331, because of the issue of federal preemption. The jurisdiction of the United States Court of Appeals for the Sixth Circuit was based upon 28 U.S.C. § 1291.

REASONS FOR GRANTING THE WRIT

I.

THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER COURTS OF APPEAL AND INTERPRETS THE STATUTE, 21 U.S.C. § 360k(a), CONTRARY TO CONGRESSIONAL INTENT AS INTERPRETED BY THIS COURT IN *MEDTRONIC, INC. v. LOHR*, 116 S. Ct. 2240 (1996).

In the short time since this Court announced its decision in *Medtronic, Inc. v. Lohr*, *id.* at least seven federal courts of appeals have issued decisions interpreting and applying one or more of the holdings of that decision: the instant case, *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997); *Wilson v. Bradlees of New England, Inc.*, 96 F.3d 552 (1st Cir. 1996); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. 1996); *Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. 1997); *Chambers v. Osteonics Corp.*, 1997 U.S. App. Lexis 6301 (7th Cir. 1997); *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997); and *Oja v. Howmedica, Inc.*, 1997 U.S. App. Lexis 7175 (10th Cir. 1997). The Sixth Circuit in *Martin* was the *only* court of appeals to hold that all of a party's state law tort claims were preempted under the principles announced by this Court in *Lohr*.

The Petitioners assert that the Sixth Circuit Court of Appeals improperly interpreted and improperly applied *Lohr* in the *Martin* case. At the very least, the decision in *Martin* differs significantly from those in the other cited cases, giving this Court more than sufficient reason to give further instruction to the lower courts in the proper interpretation and application of the preemption clause contained in the 1976 MDA.

The petitioners believe that the Sixth Circuit's understanding of this Court's opinions in *Lohr* can be fairly and simply stated as follows: If the medical device in question consists of component parts some of which have been granted an IDE exemption under the MDA and others have received a Section 510(k) "notification process" exemption, the entire device should be considered to have IDE status; and, if the device is found to have IDE status, then all state tort law claims are preempted by Section 360k(a) of the MDA. Both branches of this holding are not proper interpretations of *Lohr* and are in direct conflict with decisions in other Circuits.

In order to fully comprehend the Sixth Circuit's holdings and its judgment affirming summary judgment in Respondents' favor, it is necessary to have a clear understanding of that court's perception of the factual and procedural circumstances in *Martin*.

In its *Martin* decision, 105 F.3d 1090, at pp. 1097 and 1098 (Pet. App. A at p. 14a), that court stated:

> In their response to the motion for summary judgment, plaintiffs conceded, "[i]t is undisputed that the product system, including the defibrillator, connectors, sense/pace leads, and adapter, is currently a medical devise subject to investigational testing . . . At all times relevant to this case, the product system had secured 'investigation device exemption' (IDE) under MDA." In the same pleading, plaintiffs also conceded, in response to Telectronics' argument that plaintiffs failed to identify the defective part in the device, "[a]t issue is not what component of the product system failed;

rather, the issue is whether or not the product system failed."

The record supports the conclusion that the Y-adapter and the Model 033-572 leads were approved under the § 510(k) process. On July 14, 1989, the FDA notified Telectronics by letter of its approval of the Model 033-572 leads under § 510(k). On July 19, 1990, the FDA approved of the Telectronic Guardian ATP Model 4210 System as an investigational device. On April 1, 1991, the FDA approved the Y-adapter under the § 510(k) process.

[1] The District Court acknowledged the parties' agreement that the device was approved under the IDE and, accordingly, examined the device as a whole. The District Court, therefore, did not address the effect of the FDA's separate approval of the two component parts under the § 510(k) process. This Court in plaintiffs' first appeal similarly treated the device as a whole as an investigational device. *Martin* at 41.

On remand, apparently recognizing the advantage of classifying the defective part as approved under the § 510(k) process after *Medtronic*, plaintiffs now stress that the Y-adapter and the Model -033-572 leads were approved under the § 510(k) process. We decline, on remand, to adopt the Martins' newly constructed argument. We believe it appropriate to instead view the device as a

> whole, approved as an investigational device, as conceded by the Martins in the proceedings below.

Even though the Sixth Circuit acknowledged in detail what was contained in the record, it chose to assert the pre-*Lohr* arguments of counsel as the true facts of the case. It is impossible for attorneys as well as lower courts to anticipate what the United States Supreme Court will find relevant or important. The "facts" relevant to the § 510(k) and IDE issues in this case are not to be found in the arguments of counsel or in the opinions of lower courts, but are to be found in the documents, statutes, and regulations themselves. In comparing the dates set forth in the foregoing excerpt for the § 510(k) and IDE exemptions, it seems a bit strained for the court to find that the Y-Adapter was part of the IDE exemption process.

The Petitioners submit that the Sixth Circuit should have analyzed, interpreted and applied this Court's opinions in *Lohr* to the facts and circumstances of *Martin* as follows:

The decision of this Court in *Lohr* was a plurality decision. Justice Stevens announced the judgment of the Court and delivered the opinion of the Court with respect to Parts I, II, III, V, and VII, in which Justices Kennedy, Souter, Ginsburg and Breyer joined, and an opinion with respect to Parts IV and VI, in which Justices Kennedy, Souter and Ginsburg joined. Justice Breyer filed a separate opinion. *Medtronic*, p. 2259, in which he concurred with Parts I, II, III, V, and VII of the court's opinion and its judgment, but refused to join in Parts IV and VI of Justice Stevens' opinion. Justice O'Connor filed a separate opinion joined by Chief Justice Rehnquist, and Justices Thomas and Scalia in which she both concurred in part and dissented in part with the plurality, *Lohr*, p. 2262.

It is apparent that this Court's major struggle was in interpreting and applying the preemption section, 21 U.S.C. § 360k(a), of the 1976 MDA and the agency regulation, 21 C.F.R. § 808.1(d), promulgated pursuant to the Act, in light of the Court's previous decisions developing the doctrine of federal preemption. The decision presenting the most difficulty to this Court was *Cippolone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), a plurality decision also written by Justice Stevens interpreting the preemptive scope of the 1965 and 1969 Cigarette Smoking Acts. Medtronic tried to convince the Court to adopt its reasoning in interpreting the word "requirement" as used in 21 U.S.C. § 360k as broadly as it did in the 1965 and 1969 Smoking Acts, thereby precluding all state tort law claims under the 1976 MDA. *Medtronic*, p. 2251. Justice Stevens with concurrences of three other Justices distinguished *Cippolone*, *supra*, on the basis that the Court's interpretation of "requirement" in *Cippolone* was much more limited in its preemptive scope than that argued for by Medtronic for § 360k and as in fact specifically intended by Congress. *Medtronic*, pp. 2251-2252. Justice Breyer reached the conclusion that § 360k did not preempt the Lohrs' tort claims but did not agree with Justice Stevens in his interpretation of *Cippolone*: "I do not join Part IV, which emphasizes the differences between the MDA and the preemption statute at issue in *Cippolone*, because those differences are not, in my view, relevant in this case." *Medtronic*, pp. 2262-2263. Justice O'Connor, along with three other Justices, wanted to apply the same effect to the word "requirement" in *Medtronic* as in *Cipollone* which would have had the effect of precluding many — but not all — of the Lohrs' state tort claims. The two four-Justice groups felt that this analysis was important because the outcome of the case depended on whether the Court could turn to the agency's regulations interpreting the preemptive scope of § 360k. (*Compare* Justice Stevens at pp. 2255-2256 with Justice O'Connor at p. 2263.) A majority of the Court with the separate reasoning of Justice Breyer, *Medtronic* pp. 2260-61, held that

the Court could and would look to the Agency's interpretation of § 360k to inform the Court as to that statute's intended preemptive scope.

The primary holding in *Medtronics* is found in Part V of the decision at pp. 2257 and 2258. Part V was concurred in by five Justices. After considering the language of the statute, § 360k(a) and the regulation, 21 C.F.R. § 808.1(d) this Court stated:

> Although we do not believe that this statutory and regulatory language necessarily precludes "general" federal requirements from ever preempting state requirements, or "general" state requirements from ever being preempted, see Part VI, *infra*, it is impossible to ignore its overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be "with respect to" medical devices and "different from, or in addition to" federal requirements. State requirements must also relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and the regulations provide that state requirements of "general applicability" are not preempted except where they have "the effect of establishing a substantive requirement for a specific device." Moreover, federal requirements must be "applicable to the device" in question, and, according to the regulations, preempt state law only if they are "specific counterpart regulations" or "specific" to a "particular device."

Essentially, what this Court held was that for there to be federal preemption the state requirements *and* federal requirements must be "specific" to a "particular device". This establishes a two-prong test to be used by lower courts to determine whether a state law claim is preempted. Preemption occurs only when both conditions of specificity exist. This is what Justice Breyer agreed with in Part II of his concurring opinion *ante*, pp. 2260-2261.

Telectronics wants to read Justice Breyer's opinion as concurring with the dissent and have the majority decide that the term "requirements" as used in § 360k(a) is the same as interpreted in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). This simply is not the case, and that is principally why this Court should reverse the Sixth Circuit's case.

This Court's holding in *Lohr* applies in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), whether the "device" reached the marketplace through a § 510(k) process or an IDE process. Neither process encompasses the rule specificity or device specificity required by the holding in *Medtronic, Inc. v. Lohr*. There are no specific rules for pacemakers at this time. As Justice Stevens noted in footnote 3, *Medtronic, Inc. v. Lohr*, at p. 2247:

> 3. The FDA has not yet initiated nor suggested the initiation of a PMA process for pacemakers or most other grandfathered devices. But see 60 Fed. Reg. 41984, 41986 (1995) (pursuant to Safe Medical Devices Act of 1990, 104 Stat. 4511, calling for submission of information by February 1997 which may lead the FDA to reclassify or initiate PMA process at some time in the future for implantable pacemaker pulse generators and lead adapters).

Hence, the IDE regulations are generally applicable to Class III devices but not specifically applicable to pacemakers.

Justice Breyer disagreed with the Steven's opinion in two respects. He felt that the MDA will sometimes preempt a state law tort claim — he gave an example where state law would require a one-inch wire on a hearing aid and the federal regulation would require a two-inch wire, and opined that such state requirement would be preempted. Secondly, he found the discussion in *Cipollone*, *ante*, to be irrelevant. He agreed with the meaning and application of 21 C.F.R. § 808.1(d) as stated in the Stevens' opinion and agreed that state and federal regulation and device specificity were required for preemption. He made no distinction between § 510(k) devices and IDE devices.

The Martins' claims are very similar to those of the Lohrs. The First Cause of Action of Plaintiffs' Complaint alleges manufacturing defect under R.C. Section 2307.74. The Martins' Second Cause of Action contends that Respondent's product is defectively designed under the standards of R.C. Section 2307.75. As her Third Cause of Action, Martin pleads that Respondent inadequately warned or instructed contrary to R.C. Section 2307.76 with respect to the products. In her Fourth Cause of Action, Martin alleges that Respondent violated R.C. Section 2307.77 by nonconformance to express representation of material facts concerning the products. In her Fifth Cause of Action, she contends that Respondent is subject to liability as a supplier of the products under R.C. Section 2307.78. Mr. Martin pleads a derivative spousal claim in the Sixth Cause of Action of the complaint. A major difference between the two cases is not the nature of the claim, but rather the source of the claim under Florida and Ohio law. Under Florida tort law, the Lohrs presented their claims on the basis of common law, while the Martins were required and did state their claims based upon the statutory law of Ohio.

Effective January 5, 1988, the Ohio General Assembly enacted statutes which addressed the standards for establishing both liability and defenses for products liability damage claims for personal injury, wrongful death, and property damage. Sections 2307.71 *et seq.*, Ohio Revised Code. Copies of the relevant sections are contained in the Pet. App. G at pp. 65a-87a.

Under Section 3(B) of Amended Substitute House Bill 1 ("H.B. 1"), and pursuant to R. C. Section 2307.72, with limited exceptions, the Ohio General Assembly declared that the new statutory framework exclusively controls product liability damage claims which arise in Ohio. Announcing prospective application, Section 3(B) of H.B. 1 reads as follows:

> The provisions of sections 2307.71, 2307.72, 2307.73, 2307.74, 2307.75, 2307.76, 2307.77, 2307.78, 2307.79, 2307.80, and 2315.20 of the Revised Code as enacted by this Act and the repeal of section 2305.33 of the Revised Code by this Act shall apply only to product liability actions that are commenced on or after the effective date of this act and that are based upon claims for relief that arise on or after that date.

R. C. Section 2307.72 declares that Ohio's new statutory framework substantially replaced Ohio's common law of product liability.

Justice Stevens made clear that this Court's opinion in *Lohr* was not based on the source of the state law claims:

> These state requirements therefore escape preemption, not because the source of the

> duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements the § 360k envisioned to be "with respect to" specific devices such as pacemakers.

Medtronic, p. 2258. There is nothing in Justice Breyer's or Justice O'Connor's separate opinions indicating that they disagreed with this position. Accordingly, the Martins' claims are not preempted as a result of Ohio's statutory scheme for products liability claims.

The Petitioners submit that the foregoing analysis is a more accurate statement of this Court's intended pronouncements in *Lohr* than is the analysis of the Sixth Circuit in *Martin*. The Sixth Circuit in *Martin* did not understand the two-prong test for preemption established by this Court in *Lohr*, and misapplied the test to an IDE device with § 510(k) elements, and accordingly, wrongly decided the case.

Petitioners now turn their attention to the analysis of the various Circuit Courts of Appeals decisions cited previously:

Oja v. Howmedica, 1997 U.S. App. Lexis 7175 (10th Cir. 1997). This case involved a prosthetic hip replacement system, a device marketed under the § 510(k) notification exemption. The Tenth Circuit, unlike the Sixth Circuit, properly interpreted this Court's decision in *Lohr* as establishing a two-prong test for preemption as discussed in Petitioner's foregoing analysis. At pp. 13 and 14 of the opinion, the Tenth Circuit stated:

> *Medtronic*, 116 S. Ct. at 2256-58. The Court concluded that the statute and regulation evinced "an overarching concern that preemption occurs only where a particular

state requirement threatens to interfere with a particular federal interest." *Id.* at 2257.

Based on the MDA's statutory language and the FDA's regulation, the Court developed a two-pronged inquiry to determine the preemptive scope of the [*15] MDA. *Id.* at 2257 (quoting 21 U.S.C. § 360k). In other words, a federal requirement will preempt state law only if "specific" to a "particular device." *Id.* (quoting 21 C.F.R. § 808.1(d). Second, a state requirement must be "with respect to" a medical device and must be "different from, or in addition to" a federal requirement. *Id.* (quoting 21 U.S.C. § 360k). Accordingly, "state regulations of 'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement of a specific device.' " *Id.* (quoting 21 C.F.R. § 808.1(d)(1).

Applying the two-prong test, the Court concluded that the MDA's labeling regulations did not preempt the plaintiffs' negligent failure to warn claim. First, the Court found no preemption because the federal labeling regulations reflected "important but entirely generic concerns about device regulations generally." *Id.* at 2558. Second, the Court concluded that the negligent failure to warn claim also escaped preemption because its "generality leaves [it] outside the category of requirements that § 360k envisions [*16] to be 'with respect to' specific devices." *Id.*

In *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. 1996), the medical device at issue was a penile prosthesis. The defendant originally obtained an IDE exemption but finally marketed the device under the § 510(k) process. The Fourth Circuit analyzed the *Lohr* holding similarly to the Tenth Circuit stating on pp. 4 and 5 of the opinion:

> In sum, the rule under Medtronic is that state common-law causes of action may constitute requirements, but such requirements are preempted only when they conflict with a specific regulation promulgated by the FDA with respect to the particular device in question or a device-specific requirement imposed by the MDA. Accordingly, state-law claims pertaining to medical devices subject only to the general controls imposed by the § 510(k) notification process, GMPs, or labeling requirements are not preempted.

In *Chambers v. Osteonics Corp.*, 1997 U.S. App. Lexis 6301 (7th Cir. 1997), the medical device was a hip prosthesis, a Class III medical device granted an IDE exemption by the FDA. This decision by the Seventh Circuit is closest in its interpretation of *Lohr* to that of the Sixth Circuit in *Martin*, but even the Seventh Circuit held that a negligent manufacturing claim is not preempted by the statute.

Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997), involved the Tampax tampon, a Class II medical device for which the FDA has adopted specific regulations known as "special controls". This decision by the Ninth Circuit has some similarity in its approach to interpreting *Lohr* with the Sixth Circuit in *Martin*. However, contrary to the Sixth Circuit, the Ninth Circuit held that Plaintiff's state products liability claim was preempted

by the MDA solely because the FDA had adopted specific regulations applicable to tampons. It emphasized that the *Lohr* outcome probably would have been different if the FDA had adopted regulations specific to pacemakers.

Reeves v. Acromed, 103 F.3d 442 (5th Cir. 1997) involved metal bone plates and screws, Class III devices marketed under the § 510(k) exemption. This is a different case from *Martin*, but the Fifth Circuit properly interpreted and applied *Lohr* to permit plaintiffs to recover under a state tort law unreasonably dangerous *per se* claim.

Finally, *Wilson v. Bradlees of New England, Inc.*, 96 F.3d 552 (1st Cir. 1996), involved the issue of preemption in the context of the Flammable Fabrics Act. The First Circuit indicated it withheld decision in *Wilson* in hope of receiving further guidance from this Court in the anticipated *Lohr* decision. The First Circuit closed its opinion at page 558 with this lament:

> Resolution of this appeal was delayed in the hope that the then-anticipated decision of the Supreme Court in Lohr would provide more guidance than ultimately proved to be the case. Not only is Lohr not conclusive on our own issue, but the divisions there make even more general forecasts shaky. Absent guidance, we have done as best we can with these difficult problems of preemption in a changing legal climate. Given the time already consumed in delay in this case, the parties may want to consider whether they can reach a solution short of further litigation.

Petitioners sincerely hope along with the First Circuit that this Court will revisit its decision in *Medtronic, Inc. v. Lohr*,

116 S. Ct. 2240 (1996), and provide the much needed further guidance in the crucial area of federal preemption in general and the proper application of the preemption section of the MDA in particular.

II.

THIS CASE PRESENTS A CONSTITUTIONAL ISSUE OF FIRST IMPRESSION THAT SHOULD BE DECIDED BY THIS COURT.

What was the purpose of adding the Seventh Amendment to the United States Constitution in 1791? Does the Seventh Amendment place restrictions on Congress' powers to enact certain laws? These two questions have never been answered by this court in any context, and most particularly, this Court has never addressed the question of whether or not the doctrine of federal preemption is limited by the provisions of the Seventh Amendment.

During the past sixty years, Congress through legislation adopted pursuant to the Commerce Clause contained in Article I, Section 8 of the United States Constitution has involved the federal government in virtually every aspect of the ordinary citizen's life — from birth to death. The federal courts in most cases have permitted Congress and the federal bureaucracy to prevail under the auspices of the Supremacy Clause contained in Article VI. It seems that Congress and the courts have forgotten that the federal government was purposely created to be one of limited powers. Two of the first ten amendments make the doctrine of a limited federal government abundantly clear:

AMENDMENT IX

The enumeration in he Constitution, of

> certain rights, shall not be construed to deny or disparage others retained by the people.

AMENDMENT X

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people.

The purpose of the adoption of the Bill of Rights in 1791 was to correct what the citizens perceived as too much power being given to the federal government in the Constitution as ratified in 1787.

Each of the first ten amendments further restricted the power of the federal government to intrude in the affairs of the states and of this country's individual citizens. The Seventh Amendment provides:

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any court of the United States, than according to the rules at common law.

Petitioners submit that this Amendment places limitations on Congress that have never been considered by this court.

The Sixth Circuit in its opinion in *Martin I* acknowledged that the petitioners raised a "unique Seventh Amendment claim". It ignored the petitioners' claim stating at 70 F.3d 39, 42 (6th Cir. 1995):

> Nothing in its text or history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. The Seventh Amendment protects a litigant's right to a jury trial where there exists a cause of action at common law, or one analogous thereto, for legal relief, where the amount in controversy exceeds twenty dollars. *Tull v. United States*, 481 U.S. 412, 417-18 (1987). Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[] at common law" and the Seventh Amendment's guarantees are not implicated. We agree with the Ninth Circuit, which addressed this issue in the context of ERISA's preemption of state common-law causes of action:
>
> > Congress surely can preempt a state cause of action, be it legal or equitable: This is the very nature of federal supremacy. Once Congress has chosen to preempt the state claim, it's free to give affected individuals a full federal claim, a claim providing only for remedies limited to equity, a damages claim only, or no claim at all. The Seventh Amendment, again, does not stand in the way.
> >
> > *Spinelli v. Gaughn*, 12 F.3d 853, 858 (9th Cir. 1993) (footnote omitted).
>
> Accordingly, plaintiffs' Seventh Amendment claim must fail.

In *Martin II*, 105 F.3d 1090 (6th Cir. 1997), the Sixth Circuit again summarily disposed of the issue stating at page 1101:

> On remand, Plaintiffs contend that the Seventh Amendment right to a jury trial would be violated if this Court were to hold that their claims are preempted by the MDA. We rejected this argument in our first opinion: . . . . We see no reason to depart from our previous holding on this issue."

It is important to note that neither the Sixth Circuit nor the Ninth Circuit cited any decisions of this Court where this Court held that federal preemption is not limited by the Seventh Amendment. Those federal courts, like countless others, assumed that the Supremacy Clause has no limits. History indicates otherwise.

Congress adopted the 1938 Food, Drug, and Cosmetic Act and the 1976 Medical Device Amendments thereto pursuant to the power granted to it in the Commerce Clause contained in Article I, Section 8 of the United States Constitution. The doctrine of preemption arises from the Supremacy Clause contained in Article VI of the Constitution. Both of these provisions were in the Constitution as it was ratified in 1787.

As the Constitution was being drafted during the summer of 1787, one of the issues which stirred great debate was whether the Constitution ought to contain certain guarantees to the people, including the right to a jury trial in civil cases. Ultimately, such a provision was omitted but the omission almost caused the Constitution not to be ratified by the states. It was only the promise that the right to a jury trial in civil cases would be included in the proposed Bill of Rights that carried the day for ratification. The Antifederalists made three principle arguments in favor of the inclusion of the right to trial by jury in civil cases: the protection of debtors, the frustration of unwise legislative and administrative policies of the federal government,

and the control of corrupt judges. The right to a jury trial in a civil case was embodied in the Seventh Amendment which was ratified on December 15, 1791. (The foregoing history was abstracted from Wolfram, *The Constitutional History of the Seventh Amendment*, 57 Minnesota L. Rev. 639-747 (1973). Contrary to the assertion of the Sixth Circuit, history does support the argument that one of the purposes of the Seventh Amendment was to limit the power of Congress to pass certain laws.

This Court has historically and consistently used the historical approach in its interpretation of the Seventh Amendment. Compare Mr. Justice Story's opinion in *United States v. Wonson*, 28 F. Cas. 745, 750 (No. 16,750) (C.C.D. Mass. 1812) with Mr. Justice White's opinion writing for a unanimous court in *Wooddell v. Electrical Workers*, 116 L. Ed. 2d 419, 427 (1991), and the cases cited therein. Our modern tort law traces its history in England to the action of trespass which first appeared in the 13th century and then developed into trespass on the case which existed in England long before 1791. *See* Prosser, *Handbook of the Law of Torts*, 4th ed. West Publishing Co., 1971, p. 28. This Court has always begun its Seventh Amendment decisions by considering the common law as it existed in the 18th century, but this Court's cases have only considered whether a litigant was entitled to a jury trial in the circumstance where a cause of action was already acknowledged to exist. *See, e.g., Wooddell v. Electrical Workers, supra* (did Petitioner have a right to have his LMRDA claim tried to a jury?); *Tull v. United States*, 481 U.S. 412 (1987), (did Petitioner have a right to trial by jury on his liability and amount of penalty under the Clean Water Act?); and *Local No. 391 v. Terry*, 494 U.S. 558 (1990), (did Petitioner have a right to have his action for breach of a union's duty of fair representation determined by a jury?). None of the foregoing cases nor any other case of this court has ever determined whether or not the Seventh Amendment preserved a cause of action in and of itself.

While there is no doubt that Congress has broad power to legislate in subject areas specified in the Constitution, that power is not without limit. As the Supreme Court has said, "The touchstone of due process is the protection of the individual against arbitrary actions of the government." *Daniels v. Williams*, 474 U.S. 327, 88 L. Ed. 2d 662, 668 (1986) *quoting Dent v. W. Va.*, 32 L. Ed. 623 (1989). If Congress has provided no tort remedy for injury caused by a medical device and at the same time has preempted a state law tort claim, it has acted both arbitrarily and in contravention of the Seventh Amendment because tort claims trace their history in England to a date prior to 1791 and Congress, therefore, has no authority to prohibit the cause of action from being determined by a jury.

There is no doubt that Petitioner's Seventh Amendment claim is novel. At some point in our history all constitutional issues were novel when first raised by a party. A relatively recent example is the concept of constitutionally protected personal privacy. The term "privacy" is nowhere to be found in the United States Constitution and was not recognized as a protected right until Justice Douglas' opinion in *Griswold v. Connecticut*, 381 U.S. 479 (1965). Obviously, today it is not a novel theory, nor is there a paucity of case law espousing its importance as a concept of constitutional law.

Petitioners' position is simple and straightforward: The Seventh Amendment limits the authority of Congress to enact certain laws; Congress cannot pass a law that abrogates an individual's right to a trial by jury where the cause of action existed prior to 1791; and the Seventh Amendment as an amendment takes precedence over the Supremacy Clause. This issue is of great national importance, and accordingly, Petitioners request this Court to grant their petition and finally address this issue.

CONCLUSION

For all the reasons stated, Petitioners, Ada M. Martin and Harold L. Martin, pray that this Court grant a writ of certiorari to review the decision of the United States Court of Appeals for the Sixth Circuit.

Respectfully submitted,

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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT FILED JANUARY 31, 1997

No. 94-4003

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ADA M. MARTIN and HAROLD L. MARTIN,
Plaintiffs-Appellants,

v.

TELECTRONICS PACING SYSTEMS, INC.; TPLC, INC. d/b/a Telectronics Pacing Systems; TELECTRONICS PTY LIMITED,
Defendants-Appellees.

} ON REMAND from the United States Supreme Court

Decided and Filed January 31, 1997

Before: KENNEDY and MOORE, Circuit Judges; JOHNSTONE, District Judge.*

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*The Honorable Edward Johnstone, United States District Judge for the Western District of Kentucky, sitting by designation.

Appendix A

KENNEDY, Circuit Judge. In this products liability suit, plaintiffs, Ada and Harold Martin, appeal the District Court's summary judgment in favor of defendants, awarded largely on the basis of preemption under 21 U.S.C. § 360k(a) of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act. We previously affirmed the judgment of the District Court. *Martin v. Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995). Thereafter, the United States Supreme Court granted plaintiffs' petition for writ of certiorari, vacated our prior judgment, and remanded the case to our Court for further consideration in light of its decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). *Martin v. Telectronics Pacing Sys., Inc.*, 116 S. Ct. 2576 (1996). Pursuant to the Supreme Court's order, the case is again before us for our determination.

I.

Factual Background

The plaintiffs filed suit against Telectronics Pacing Systems, Inc. ("Telectronics") after Ada Martin suffered injuries resulting from the implantation of the Telectronics Guardian ATP 4210 Implantable Cardioverter-Defibrillator-Demand Pacemaker ("device"). The device, which combines the functions of a defibrillator, a cardioverter, and a pacemaker, was one of fifty such experimental devices. The device is implanted into the patient's body and generates electrical shocks, when necessary, to maintain a normal heart rhythm.

On the morning of March 31, 1992, Ada Martin signed a form consenting to implantation of the device to correct a heart ailment. Later that day, doctors at the Ohio State University Hospitals implanted the device into Ada Martin's chest. Plaintiffs claim that the device began to malfunction sometime after the operation and was therefore replaced in a subsequent operation on November 19, 1992. As a result of the alleged malfunction of the device, the Martins claim that they suffered $500,000 in damages.

Appendix A

Plaintiffs allege five causes of action under Ohio products liability law pursuant to Ohio Revised Code §§ 2307.74 - .78. The Complaint alleges that the defendant (1) defectively manufactured the device; (2) defectively designed the device; (3) failed to adequately warn plaintiffs; (4) failed to conform to certain unidentified "express representations;" and (5) supplied the device in question to plaintiffs. Ada Martin's spouse also pleaded a derivative common-law tort claim alleging that he suffered loss of consortium and companionship as a result of the defendant's conduct.

Telectronics filed for summary judgment on all of the plaintiffs' claims arguing that they were preempted by section 360k(a) of the Medical Device Amendments. The District Court granted Telectronics' motion. On appeal, we affirmed the judgment of the District Court and held that all of plaintiffs' claims were preempted. Additionally, we held that the finding of preemption did not violate the plaintiffs' Seventh Amendment right to a jury trial. Subsequently, plaintiffs petitioned the United States Supreme Court for a writ of certiorari. Their petition was granted and the Supreme Court remanded the case to our Court for reconsideration in light of the Court's decision in *Medtronic, Inc. v. Lohr*, *supra*.

II.

Standard of Review

Despite the Supreme Court's order vacating and remanding the case for our redetermination, our standard of review remains unchanged. This Court's review of a grant of summary judgment is *de novo*; it uses the same test as used by the District Court. *See Brooks v. American Broadcasting Cos.*, 932 F.2d 495, 500 (6th Cir. 1991), *cert. denied*, 510 U.S. 1015 (1993). In reviewing summary judgment motions, courts must view the evidence in the light most favorable to the nonmoving party to determine whether a genuine issue of material fact exists. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). Under FED. R. CIV. P. 56(c), summary judgment is proper

if the evidence "'show[s] that there is no genuine issue as to any material fact and that the moving party is entitled to [a] judgment as a matter of law.'" *Canderm Pharmacal, Ltd. v. Elder Pharmaceuticals, Inc.*, 862 F.2d 597, 601 (6th Cir. 1988)(quoting FED. R. CIV. P. 56(c)).

III.

Medtronic, Inc. v. Lohr

In *Medtronic, Inc. v. Lohr*, the Supreme Court was presented for the first time with the question of whether the MDA preempts state common law actions against the manufacturer of an allegedly defective medical device. Lora Lohr and her husband filed suit against Medtronic alleging strict liability, negligent design, negligent manufacturing, and inadequate labeling under Florida state law after Lora Lohr was implanted with a pacemaker manufactured by Medtronic which contained an allegedly defective lead. The pacemaker lead was exempted from the rigorous premarket approval ("PMA") process under the § 510(k) process for substantially equivalent devices. *Medtronic* at 2248. After the defendant removed the case to federal court, Medtronic moved for summary judgment arguing that all of the plaintiffs' claims were preempted under § 360k(a). That section provides:

> § 360k. State and local requirements respecting devices
> (a) General rule
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Appendix A

21 U.S.C. § 360k(a).

The district court initially denied the motion. However, soon after its decision, the United States Court of Appeals for the Eleventh Circuit in an unrelated case held that § 360k required preemption of at least some common law claims. Thereafter, the district court reconsidered its prior ruling and dismissed the plaintiffs' complaint. *Id.* at 2249. The Eleventh Circuit reversed, in part, holding that the Lohrs' negligent design claim and their strict liability claim arising from an unreasonably dangerous design were not preempted by the MDA. The Eleventh Circuit upheld the dismissal of the Lohrs' negligent manufacturing and negligent failure to warn claims on preemption grounds. *Id.* The Supreme Court granted Medtronic's petition and the Lohrs' cross-petition for certiorari in light of the division amongst the circuit courts over the extent to which common law claims are preempted by the MDA. *Id.* at 2250.

In a five to four decision, the Court held that none of the plaintiffs' common law claims were preempted by the MDA. *Id.* at 2258. The plurality opinion was authored by Justice Stevens and was joined by Justices Kennedy, Souter, and Ginsburg. Justice Breyer wrote a separate opinion, concurring in part and concurring in the judgment, in which he joined in five of seven parts of Justice Stevens' opinion. Thus, the five sections joined by Justice Breyer (Sections I, II, III, V, and VII) constitute the opinion of the Court.

In determining the extent to which the MDA preempts state common law claims, the Court first noted that, while § 360k(a) is an express preemption provision in the MDA, the scope of federal preemption under § 360k(a) is ambiguous. *Id.* at 2255. This ambiguity in addition to Congress' express grant of authority to the Food and Drug Administration ("FDA") to implement the MDA, in the Court's opinion, rendered the FDA's interpretation of the statute entitled to substantial weight. *Id.* at 2256. According to FDA regulations:

> State or local regulations are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not 'requirements applicable to a device' within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electric codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.
> (2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d)(1996).

Based on this language, the Court concluded that the statutory and regulatory language mandate that preemption occur only when the state and federal requirements meet certain criteria. A state requirement must be "'with respect to'" a medical device and must be "'different from, or in addition to'" federal requirements. *Medtronic* at 2257. Moreover, the state requirement must relate "'to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.'" *Id.* Finally, "[s]tate regulations of 'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement of a specific device.'" *Id.* The federal requirement "must be 'applicable to the device' in question . . . and preempt state law only

if they are 'specific' to a 'particular device.'" *Id.* The Court divided on whether state common law actions could ever be preempted by the MDA. Significantly, a majority of the Court held that such actions do impose "requirements" under the MDA and are therefore preempted when the other conditions, as aforementioned, are satisfied. *Id.* at 2262.

Regarding the specific claims brought by the Lohrs, the Court held that none of their claims were preempted. *Id.* at 2259. With respect to the defective design claim, the Court concluded that, because the device was approved pursuant to the § 510(k) process, the device was never reviewed for safety and efficacy. Thus, because the § 510(k) process did not impose a federal "requirement," the claim was not preempted. *Id.* at 2254.

Regarding the manufacturing and labeling claims, the Court rejected Medtronic's argument that federal regulations governing the labeling and manufacture of all medical devices were federal "requirements." The Court rejected the argument because federal labeling and manufacturing regulations "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns" contemplated by the preemption provision of the MDA. *Id.* at 2258. Furthermore, the state common law requirements were not specifically developed "with respect to" medical devices and were not "the kinds of requirements that . . . would impede . . . the implement[ation] and enforce[ment] [of] specific federal requirements." *Id.* at 2258. The state requirement regarding negligent manufacturing was simply "the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products." *Id.* at 2258. Similarly, the "failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Id.* Thus, none of these state requirements were "with respect to" a medical device. Accordingly, none of the plaintiffs' claims were preempted.

Lastly, the Court concluded that if further development of the record and the plaintiffs' theories of recovery revealed that the Lohrs' action included a claim that Medtronic failed to comply with FDA regulations, that claim would not be preempted because "nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 2255.

IV.

A. PMA, § 510(k) Process, and IDE

The MDA comprehensively regulates medical devices. Within the comprehensive regulations, the FDA classifies medical devices intended for human use into three categories based on the degree of regulation necessary to assure the device's safety and effectiveness. 21 U.S.C. § 360c. Class III[1] devices are subject to the most stringent controls as they present a "potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(1)(C). In order to market a Class III device, a manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. 21 U.S.C. § 360e(d)(2). To prove that the device is reasonably safe and effective, the manufacturer must obtain premarket approval ("PMA") through a long process that requires the manufacturer to submit to the FDA detailed information about the safety and effectiveness of the device. *Medtronic* at 2246-47. The manufacturer must submit a bibliography of all reports concerning the device's safety and effectiveness, an outline of the device's components and properties, a description of the manufacturing process, safety data, samples of the device, and copies of all proposed labeling. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20 (1996). As noted by the Supreme Court in *Medtronic*, the FDA then reviews the

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[1]The device at issue in the instant case would be classified as a Class III device as pacemakers are Class III devices. *Medtronic* at 2246; 21 C.F.R. § 870.3610 (1995).

information spending an average of 1200 hours on each submission. *Id.* at 2246.

There are exceptions to the PMA requirement which manufacturers may utilize to avoid the rigorous PMA process, two of which are relevant to the case at hand. First, the MDA allows devices that are "substantially equivalent" to preexisting devices to avoid the PMA process in order to permit them to compete with devices that were on the market prior to 1976 when the MDA was enacted. 21 U.S.C. § 360e(b)(1)(B). This was the exception at issue in *Medtronic*. Manufacturers of "substantially equivalent" Class III devices must submit to a limited form of review known as "premarket notification" or "the § 510(k) process" which allows the device to be marketed without inquiry and without submitting much information if the FDA determines that the device is substantially equivalent to a preexisting device. *Medtronic* at 2247. In contrast to the lengthy PMA process, the 510(k) process is completed in an average of only 20 hours. *Medtronic* at 2247.

A second exception exempts investigational devices from the PMA process in order "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use." 21 U.S.C. § 360j(g). This exception is called the "Investigational Device Exemption" ("IDE"). Although investigational devices are not subject to the rigorous PMA process, they are subject to a different set of complex and comprehensive regulations which set forth detailed procedures for determining whether investigational devices are safe and effective. *See* 21 U.S.C. § 360j(g)(3); 21 C.F.R. §§ 812.20, 812.25, 812.27 (1996).

To obtain approval of a device under the IDE, a manufacturer must submit an application to the FDA containing an abundance of information. Pursuant to 21 C.F.R. § 812.20, the manufacturer must submit an application setting forth a complete report of all prior

investigations and a "description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can made a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 812.20.

Pursuant to 21 C.F.R. § 812.25, the manufacturer must submit a detailed statement regarding the intended use of the device and the objectives and planned duration of the investigational study; a written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound; an analysis of all risks involved; a description of each component, ingredient, property, and principle of operation of the device; a detailed description of the methods, facilities and controls used for manufacturing, processing, packing, storing and installing the device; sample agreements between the manufacturers and all proposed investigators; detailed information about the health care professionals and institutions participating in the investigation; proposed labeling; proposed informed consent forms; and a full set of written procedures for monitoring the investigation, including record and report maintenance. Pursuant to 21 C.F.R. § 812.27, the manufacturer must submit a bibliography of every publication relevant to the evaluation of the device and information from non-clinical testing.

Based on the information submitted, the FDA will approve the device under the IDE unless "the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective." 21 C.F.R. § 812.30. Once the device is approved under the IDE, the device is exempted from, among other things, compliance with performance standards and good manufacturing practice requirements. 21 C.F.R. § 812.1(a).

Appendix A

B. Telectronics' Device

The Medtronic device's exemption from the PMA process by way of the § 510(k) notification process was central to the outcome of *Medtronic*. Justice Stevens, speaking for the Court, recognized that the § 510(k) process is "focused on equivalence, not safety," and as a result, "substantial equivalence determinations provide little protection to the public." *Medtronic* at 2254. Having concluded that the device implanted into Lohr was never formally reviewed under the MDA for safety and efficacy because it was not approved pursuant to the PMA process, the Court held that the Lohrs' design defect claim was not preempted. *Id.* at 2255. Furthermore, although Justice Stevens noted in Part VI of his opinion that "few, if any, common-law duties have been preempted by this [§360k] statute," *id.* at 2258, this statement garnered strong criticism from five other members of the Court and was, thus, not joined by a majority of the Court. The opinions of Justice Breyer and O'Connor suggest that design claims involving devices approved outside of the § 510(k) process may be preempted. For example, Justice Breyer posed an example of a hypothetical MDA regulation requiring use of a 2-inch wire in a device with a hypothetical "award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent." *Id.* at 2259. Using this example, he concluded that if the hypothetical provision in the MDA would preempt a state regulation of a 1-inch wire, then the MDA would have to preempt a similar requirement embodied in a standard of care or behavior. *Id.*

Justice O'Connor, joined by the Chief Justice, Justice Scalia and Justice Thomas, agreed. Justice O'Connor opined that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." *Id.* at 2262. Justice O'Connor, however, agreed that the Lohrs' defective design claim was preempted because the device was approved through the § 510(k) process and that process "merely evaluates whether the

Class III device at issue is substantially equivalent to a device that was on the market before 1976, the effective date of the Medical Device Amendments" and therefore does not place any 'requirements' on the device." *Id.* at 2263. Regarding the manufacturing and labeling claims, Justice O'Connor would not subscribe to the plurality's requisite of "specificity." In her view, the common law claims would be preempted because, if successful, they would impose state requirements different from or in addition to the comprehensive federal requirements regarding manufacturing set out in the FDA's Good Manufacturing Practice, 21 C.F.R. §§ 820.20-820.198 (1996), and labeling set out at 21 C.F.R. § 801.109. Thus, although Justice Breyer agreed with Justice Stevens' opinion imposing a specificity requirement, a majority of the Court (Justices Breyer, O'Connor, Scalia, Thomas, and Chief Justice Rehnquist) agreed that the MDA preemption provision could preempt state law causes of action where the state law differs from or is in addition to requirements imposed by the MDA.

Unlike the general federal requirements discussed in *Medtronic*, the regulations governing investigational devices are essentially device specific. There are no specific regulations governing pacemakers like the one at issue; however, the application and approval process under the IDE is device specific. For example, the FDA requires information regarding "the methods, facilities, and controls used for manufacture . . . of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 812.20(b)(3). The FDA then exempts the device, if approved, from the general requirements of good manufacturing practice that would ordinarily apply. 21 C.F.R. § 812.1(a). In reviewing the application, the FDA calculates the risks and benefits of the particular device and grants an exemption only if the risks are outweighed by the benefits to the subjects. 21 C.F.R. § 812.30(b)(4).

It is, thus, imperative that we determine whether the device at issue was approved as an investigational device or through the § 510(k) process. The plaintiffs contend that Ms. Martin's injuries were likely caused by a part of the device called the Y-adapter[2] and they contend that the Y-adapter was approved under the § 510(k) process.[3] They claim that neither the Y-adapter nor the Model 033-572 leads were included in the IDE granted to Telectronics for the 4210 system. It was not included, they argue, because Telectronics had received a § 510(k) substantially equivalent exemption for the Y-adapter[4] and for the leads of the device.

As Telectronics notes, the record reveals that, in its motion for summary judgment as to the Model 033-572 leads and the Y-adapter,[5] Telectronics argued in the alternative. It first argued that the leads and the adapter were approved by the FDA pursuant to the § 510(k) premarket notification procedure and that claims against devices approved under § 510(k) are preempted. Alternatively, it argued that, although the two component parts were approved under the § 510(k) process, the device

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[2]Before the trial court, plaintiffs contended that the device's malfunction was caused by either the Model 033-572 right sense/pace lead or the Y-adapter.

[3]The device contains four component parts: (1) Model 4210 defibrillator; (2) Model 040-106 leads; (3) Model 033-572 leads; and (4) Model 033-415 Y-adapter.

[4]The record indicates, however, that Telectronics received the substantially equivalent exemption for the Y-adapter after it received the IDE for the entire device.

[5]Telectronics filed two separate motions for summary judgment. The first was filed as to the defibrillator and Model 040-106 defibrillator leads. The court granted Telectronics' motion regarding those devices. The second motion, which was also granted, was filed as to the Model 033-572 leads and the Y-adapter.

as a whole was approved under IDE, and claims against devices approved under the IDE are preempted.

In their response to the motion for summary judgment, plaintiffs conceded, "[i]t is undisputed that the product system, including the defibrillator, connectors, sense/pace leads, and adapter, is currently a medical device subject to investigational testing . . . At all times relevant to this case, the product system had secured 'investigation device exemption' (IDE) under MDA." In the same pleading, plaintiffs also conceded, in response to Telectronics' argument that plaintiffs failed to identify the defective part in the device, "[a]t issue is not what component of the product system failed; rather, the issue is whether or not the product system failed."

The record supports the conclusion that the Y-adapter and the Model 033-572 leads were approved under the § 510(k) process. On July 14, 1989, the FDA notified Telectronics by letter of its approval of the Model 033-572 leads under § 510(k). On July 19, 1990, the FDA approved of the Telectronic Guardian ATP Model 4210 System as an investigational device. On April 1, 1991, the FDA approved the Y-adapter under the § 510(k) process.

The District Court acknowledged the parties' agreement that the device was approved under the IDE and, accordingly, examined the device as a whole. The District Court, therefore, did not address the effect of the FDA's separate approval of the two component parts under the § 510(k) process. This Court in plaintiffs' first appeal similarly treated the device as a whole as an investigational device. *Martin* at 41.

On remand, apparently recognizing the advantage of classifying the defective part as approved under the § 510(k) process after *Medtronic*, plaintiffs now stress that the Y-adapter and the Model 033-572 leads were approved under the § 510(k) process. We decline, on remand, to adopt the Martins' newly constructed argument. We believe it appropriate to instead view the device as a whole,

approved as an investigational device, as conceded by the Martins in the proceedings below.

V.

Plaintiffs' Causes of Action After *Medtronic*[6]

A. Manufacturing Defect

Count I of Plaintiffs' complaint asserts a manufacturing defect claim pursuant to Ohio Revised Code § 2307.74 which provides:

> A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

Ohio Rev. Code Ann. § 2307.74 (Anderson 1995). To preempt this claim, the federal requirement regarding manufacturing "must be 'applicable to the device' in question . . . and 'specific' to a 'particular device.'" *Medtronic* at 2257. As discussed above, the regulations

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[6]No other circuit court has yet had the opportunity to decide whether state causes of action for injuries caused by investigational devices are preempted by the MDA after *Medtronic*. However, one federal district court held that state law claims sounding in strict liability and negligence were preempted in a case involving a prosthetic hip replacement approved as an investigational device. *See Berish v. Richards Medical Co.*, 937 F. Supp. 181 (N.D.N.Y. 1996). In contrast, the Missouri Supreme Court held that causes of action for negligence, strict liability, failure to warn, lack of informed consent, and fraud were not preempted in a case involving an intraocular lens implant approved as an investigational device. *See Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996).

governing manufacturing of the device at issue in this case are specific to investigational devices. Unlike the manufacturing claim in *Medtronic*, where the federal manufacturing regulations "reflect[ed] important but entire generic concerns about device regulation generally, not the sort of concerns" contemplated by the preemption provision of the MDA, *id.* at 2258, the regulations governing manufacturing at issue here specifically apply to investigational devices.

In order to preempt this claim, however, the state requirement must be "'with respect to'" a medical device as well as "'different from, or in addition to'" federal requirements. *Id.* at 2257. Moreover, the state requirement must relate "'to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.'" *Id.* "State regulations of 'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement of a specific device.'" *Id.*

Given that the FDA specifically approves of the manufacturing adequacy of the device for investigational purposes under 21 C.F.R. § 812.30(b)(5) and exempts an investigational device from the good manufacturing requirements normally applicable to devices approved under the PMA process, the state statute applies a requirement different from that imposed by federal law. However, it is questionable whether the statute is "with respect to" a medical device and not simply of general applicability. In *Medtronic*, the state common law requirements regarding manufacturing were not specifically developed "with respect to" medical devices and were not the kinds of requirements that would impede the implementation and enforcement of specific federal requirements. *Medtronic* at 2258. The state requirement regarding negligent manufacturing was simply "the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products." *Id.* at 2258. The same cannot be argued with respect to the generally applicable statute in question because it is the kind of

requirement that would impede the implementation and enforcement of specific federal requirements. *Id.* The purpose of the exemption for investigational devices is to promote safety and innovation, the twin aims of the investigational device exemption of the MDA. To allow a cause of action for a manufacturing defect under state law where the FDA has specifically exempted an investigational device from Good Manufacturing regulations would thwart the goals of the IDE exemption "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use." 21 U.S.C. § 360j(g). We, therefore, hold that the Martins' manufacturing defect cause of action is preempted.

B. Design Defect

Plaintiffs' design defect claim asserted in Count II of their complaint arises from Ohio Revised Code § 2307.75 which provides, in part:

> a product is defective in design . . if either of the following applies:
> (1) When it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design . . .
> (2) It is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

Ohio Rev. Code Ann. § 2307.75.

It is this claim that most sharply differs from the analysis of the design defect claim in *Medtronic*. With respect to the Lohrs' defective design claim in *Medtronic*, the Court concluded that, because the device was approved pursuant to the § 510(k) process, the device was never reviewed for safety and efficacy. Thus, because the § 510(k) process did not impose a federal "requirement," the claim was not preempted. *Medtronic* at 2254. In stark contrast, the device at issue here was approved as an investigational

device and its risks and benefits were specifically reviewed and balanced in accordance with 21 C.F.R. § 812.30. Thus, because under the federal requirement the FDA has determined that the benefits of the device outweigh the risks and, under the state requirement, a jury in a state court action could conclude that the risks outweigh the benefits, the state requirement is different from the federal requirement. In addition, subsection two of Ohio Revised Code § 2307.75 regarding consumer expectations is a requirement "in addition" to the requirements of the federal regulations.

We again face the question of whether the state requirement was developed "with respect to" medical devices. Again, the state requirement appears not specifically applicable solely to medical devices. However, the state statute is the kind of requirement that would impede the implementation and enforcement of specific federal requirements. *Medtronic* at 2258. To allow a cause of action for design defect where the FDA has specifically approved of the design of the device for investigational purposes would thwart the goals of safety and innovation. Accordingly, Count II of Plaintiffs' complaint is similarly preempted.

C. Inadequate Warning

Plaintiffs' inadequate warning claim arises from Ohio Revised Code § 2307.76. Section 2307.76 generally provides that a product is defective where the manufacturer fails to issue adequate warnings when the manufacturer knew or, in the exercise of reasonable care, should have known of a risk of harm to the consumer. The federal regulations regarding investigational devices set forth several requirements concerning warnings. First, the label on an investigational device must bear a warning that the device is for investigational purposes only and must describe "all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions." 21 C.F.R. § 812.5(a). In addition, during the application process, the manufacturer must submit the

label to the FDA for its review. 21 C.F.R. § 812.25(f). Most importantly, during the application process, the manufacturer must submit the consent form to be signed by the subject. 21 C.F.R. § 812.25(g).

Ms. Martin reviewed and signed the consent form reviewed by the FDA in the case at hand. The consent form notified Ms. Martin, *inter alia*: (1) that the cardioverter/defibrillator was an investigational device not yet approved by the FDA; (2) of the availability of an alternative FDA approved device; (3) of the risks of the device such as repeat operation and component failure; and (4) that there may be clinical or technical reasons for failure of the device not currently known.

The Supreme Court in *Medtronic* rejected Medtronic's argument that federal regulations governing the labeling of all medical devices were federal "requirements." The Court rejected the argument because federal labeling regulations "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns" contemplated by the preemption provision of the MDA. *Medtronic* at 2258. Unlike in *Medtronic*, the labeling requirements here are specific in that they apply only to investigational devices; they are not, therefore, generic requirements.

Like in *Medtronic*, the state requirement here was not specifically developed "with respect to" medical devices. As noted in *Medtronic*, the "failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Id.* However, the arguments articulated in connection with the manufacturing and design defect claims apply as well to the inadequate warning claim. Namely, the state requirement would impede the implementation and enforcement of specific federal requirements. To allow a state cause of action for inadequate warnings would impose different requirements or requirements in addition to those required by federal regulations. Such requirements would impede Congress' intent in enacting the investigational device

exemption to promote the development of medical devices for human use to the extent consistent with safety to human life.

D. Nonconformance to Express Representations

Count IV of Plaintiffs' complaint alleges that Telectronics is liable under § 2307.77 of the Ohio Revised Code for failure to conform to express representations. Section 2307.77 states:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

Ohio Rev. Code Ann. § 2307.77. We addressed this claim in detail in our previous opinion:

> We conclude that, in the context of investigational devices, express warranty claims are also preempted.
>
> Express representations made about investigational devices are subject to comprehensive FDA regulation. For example, 21 C.F.R. § 812.5 mandates the contents of investigational device labels; § 812.7 prevents the commercialization and promotion of investigational devices, and prohibits any representation that "an investigational device is safe or effective for the purposes for which it is being investigated"; and § 812.25(f) requires submission of all investigational device labeling to the FDA for approval. Thus, the representations that can, cannot, and must be made about an investigational device are all determined by the FDA.
>
> Plaintiffs' [sic] advance an express warranty claim under state law of "nonconformance to express representational concerning the character, quality, and/or safety of the device." Because such a claim

> would, in effect, impose a requirement "different from or in addition to" an FDA regulation "which relates to the safety or effectiveness of the device," we hold that it is preempted by § 360k(a).

Martin at 42 (citations omitted). The intervening decision in *Medtronic* does not change our analysis as *Medtronic* did not involve a breach of warranty claim and nothing expressed in *Medtronic* compels us to reach a different result. As indicated by *Medtronic* and as conceded by defendant, a claim that Telectronics did not comply with MDA regulations governing its device would not be preempted and the Martins could pursue a remedy in state court. However, plaintiffs failed to allege below that Telectronics did not comply with MDA regulations governing devices approved under the IDE. Thus, any remedy available to the Martins under a failure to comply with federal regulations theory has been waived.

E. Supplier Liability

Under Ohio Revised Code § 2307.78, a supplier is subject to liability if:

> (1) The supplier in question was negligent and that negligence was a proximate cause of harm for which the claimant seeks to recover compensatory damages;
>
> (2) The product in question did not conform, when it left the control of the supplier in question, to a representation made by that supplier, and that representation and the failure to conform to it were a proximate cause of harm for which the claimant seeks to recover compensatory damages.

Ohio Rev. Code Ann. § 2307.78(A). Plaintiffs claim that Telectronics is liable under this section as a supplier of the device. Both methods of imposing liability articulated in this section are inextricably linked to the causes of action discussed previously and are, thus, preempted for the same reasons: under subsection (1), a claim that Telectronics was negligent in its manufacturing, design, or labeling is

preempted; under subsection (2), a claim that Telectronics failed to conform to a representation is similarly preempted.

F. Derivative Spousal Claims

The final claim of plaintiffs' complaint is brought by Harold Martin for loss of consortium and companionship. Because this claim is derivative of preempted claims, summary judgment was properly granted on behalf of Telectronics.

VI.

Seventh Amendment

On remand, plaintiffs contend that their Seventh Amendment right to a jury trial would be violated if this Court were to hold that their claims are preempted by the MDA. We rejected this argument in our first opinion:

> Nothing it its text of history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. The Seventh Amendment protects a litigant's right to a jury trial where there exists a cause of action at common law, or one analogous thereto, for legal relief, where the amount in controversy exceeds twenty dollars. Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[] at common law" and the Seventh Amendment's guarantees are not implicated.

Martin at 42 (citations omitted). We see no reason to depart from our previous holding on this issue.

VII.

Conclusion

For the foregoing reasons, we **AFFIRM** the judgment of the District Court.

APPENDIX B — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT FILED JANUARY 31, 1997

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No: 94-4003

ADA M. MARTIN and HAROLD L. MARTIN,

Plaintiffs-Appellants,

v.

TELECTRONICS PACING SYSTEMS, INC.; TPLC, INC., doing business as Telectronics Pacing Systems; TELECTRONICS PTY LIMITED,

Defendants-Appellees.

Before: **Kennedy** and **Moore**, Circuit Judges;
Johnstone, Senior District Judge.

JUDGMENT

UPON CONSIDERATION of the opinion of the United States Supreme Court and reconsideration of the original opinion, judgment of this court, and the supplemental briefs.

THIS CAUSE was heard on the record from the district court and was reargued by counsel.

Appendix B

IN CONSIDERATION WHEREOF, it is ORDERED that the judgment of the district court is AFFIRMED.

ENTERED BY ORDER OF THE COURT

s/ Leonard Green
Leonard Green, Clerk

Issued as Mandate: February 24, 1997

A True Copy.
Attest:

s/ illegible
Deputy Clerk

COSTS: None

Filing Fee ..... $
Printing ..... $
Total ..... $

APPENDIX C — DECISION OF THE SUPREME COURT OF THE UNITED STATES DATED JULY 1, 1996

Ada M. MARTIN, et vir, petitioners,
v. TELECTRONICS PACING
SYSTEMS, INC., et al.

No. 95-1336.

July 1, 1996.

Case below, 70 F.3d 39.

On petition for writ of certiorari to the United States Court of Appeals for the Sixth Circuit. Petition for writ of certiorari granted. Judgment vacated, and case remanded to the United States Court of Appeals for the Sixth Circuit for further consideration in light of *Medtronic, Inc. v. Lohr*, 518 U.S. __, 116 S.Ct. 2240, __ L.Ed.2d __ (1996).

APPENDIX D — DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT FILED NOVEMBER 20, 1995

No. 94-4003

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

ADA M. MARTIN; HAROLD L. MARTIN,

Plaintiffs-Appellants,

v.

TELECTRONICS PACING SYSTEMS, INC., et al.,

Defendants-Appellees.

ON APPEAL from the United States District Court for the Southern District of Ohio

Decided and Filed November 20, 1995

Before: KENNEDY and MOORE, Circuit Judges; JOHNSTONE, District Judge.*

KENNEDY, Circuit Judge. Plaintiffs, Ada and Harold Martin, appeal from a grant of summary judgment for defendants in this diversity action alleging state product liability and related tort claims arising out of the implantation of an experimental medical device. The District Court held that federal law

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* The Honorable Edward H. Johnstone, United States District Judge for the Western District of Kentucky, sitting by designation.

preempted plaintiffs' claims. Plaintiffs appeal this decision and also argue in the alternative that if their claims are preempted, it is a violation of their Seventh Amendment right to a jury trial. We disagree, and for the following reasons AFFIRM the decision of the District Court.

I.

Medical devices intended for human use are heavily regulated by the Food and Drug Administration pursuant to the Medical Device Amendments to the Food, Drug and Cosmetics Act ("MDA"), 21 U.S.C. § 360c. In order "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use," the MDA exempts certain "investigational devices" from FDA performance standards and premarket approval. 21 U.S.C. § 360j(g).[1] Investigational devices are instead subject to a different set of complex and comprehensive regulations. *See, e.g.*, 21 U.S.C. § 360j(g)(3); 21 C.F.R. §§ 812.20, 812.25, 812.27.

The Telectronics Guardian ATP 4210 Implantable Cardioverter-Defibrillator-Demand Pacemaker ("device") is an investigational medical device not yet approved by the FDA for general release to the marketplace. It combines the functions of a defibrillator, a cardioverter, and a pacemaker. The device is implanted into the patient's body and generates electrical shocks, when necessary, to maintain a normal heart rhythm.

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1. Were it not for its investigational status, the product at issue would have been regulated as a Class III medical device. *See* 21 C.F.R. §§ 870.3610, 870.3680, 870.5300.

Appendix D

On the morning of March 31, 1992, plaintiff Ada Martin signed a form consenting to implantation of the device to correct a heart ailment. Later that day, doctors at the Ohio State University Hospitals implanted the device into Ada Martin's chest. Plaintiffs claim that the device began to malfunction sometime after the operation and was therefore replaced in a subsequent operation on November 19, 1992. As a result of the alleged malfunction of the device, plaintiffs claim that they have suffered $500,000 in damages.

Plaintiffs allege five causes of action under Ohio products liability law, Ohio Rev. Code §§ 2307.74-.78. Specifically, the complaint alleges that the defendant (1) defectively manufactured the device; (2) defectively designed the device; (3) failed to adequately warn plaintiffs; (4) failed to conform to certain unidentified "express representations"; and (5) supplied the device in question to plaintiffs. Ada Martin's spouse also pleaded a derivative common-law tort claim alleging that he suffered loss of consortium and companionship as a result of defendant's conduct.

Defendant filed for summary judgment on these claims arguing that they were preempted by MDA § 360k(a).[2] In

2. This section states, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(Cont'd)

response, plaintiffs sought a declaration that their state claims were not preempted. In a series of two opinions and orders, the District Court granted defendant's motion, holding that § 360k(a) preempted plaintiffs' claims. Plaintiffs now appeal, arguing that the District Court erred in holding that their claims were preempted and, alternatively, that if their claims are preempted, the MDA violates their Seventh Amendment right to a jury trial.[3]

II.

The issue raised by plaintiffs' first argument is whether MDA § 360k(a) preempts their state law products liability and derivative state common-law claims. Several courts of appeals have previously addressed this question and have held similar state law claims preempted. *See Mitchell v. Collagen Corp.*, No. 94-3946, 195 WL 576949 (7th Cir. Oct. 2, 1995); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995); *Martello v. CIBA Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540

(Cont'd)

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

3. Appellants also raise a Fifth Amendment substantive due process argument. However, this argument was not raised before the District Court and it has therefore been waived. *Bricker v. Voinovich*, 977 F.2d 235, 238 (6th Cir. 1992), *cert. denied*, 113 S. Ct. 2965 (1993).

(3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993). *But see Kennedy v. Collagen Corp.*, No. 94-15197, 1995 WL 606511 (9th Cir. Oct. 17, 1995) (holding state law claims not preempted where FDA had established no specific requirements unique to the Class III medical device at issue). We now join the majority of circuits and hold that § 360k(a) of the MDA expressly preempts plaintiffs' state law product liability claims.

There is disagreement as to whether this section also preempts claims for breach of an express warranty. *Compare King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.) (holding express warranty claims preempted), *cert. denied*, 114 S. Ct. 84 (1993) *and Duvall*, 65 F.3d at 400-01 (holding express warranty claims based on FDA-mandated labeling, packaging, or advertising preempted) *with Michael v. Shiley, Inc.*, 46 F.3d 1316, 1327 (3rd Cir.) (holding express warranty claims not preempted), *cert. denied*, 116 S. Ct. 67 (1995) *and Mitchell*, __ F.3d at __ (following *Michael*). We conclude that, in the context of investigational devices, express warranty claims are also preempted.

Express representations made about investigational devices are subject to comprehensive FDA regulation. For example, 21 C.F.R. § 812.5 mandates the contents of investigational device labels; § 812.7 prevents the commercialization and promotion of investigational devices, and prohibits any representation that "an investigational device is safe or effective for the purposes for which it is being investigated"; and § 812.25(f) requires submission of all investigational device labeling to the FDA for approval. Thus, the representations that can, cannot, and must be made about an investigational device are all determined by the FDA.

Appendix D

Plaintiffs' advance an express warranty claim under state law of "nonconformance to express representations concerning the character, quality, and/or safety of the device." Because such a claim would, in effect, impose a requirement "different from or in addition to" an FDA regulation "which relates to the safety or effectiveness of the device," we hold that it is preempted by § 360k(a). *See Duvall*, 65 F.3d at 40-01; *King*, 983 F.2d at 1135. *See also Talbott*, 63 F.3d at 31 (reaffirming *King*).

We now turn to plaintiff's unique Seventh Amendment claim.

III.

The Seventh Amendment states, in relevant part: "In suits at common law, where the value in controversy shall exceed twenty dollars, the right of a trial by jury shall be preserved . . . ." U.S. Const. amend. VII. Plaintiffs interpret this to mean that the federal government cannot preempt a state tort remedy if it provides no analogous tort remedy at federal law "because tort claims trace their history in England to a date prior to 1791 and Congress, therefore, has no authority to prohibit the cause from being considered by a jury."

We disagree. Nothing in its text or history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. The Seventh Amendment protects a litigant's right to a jury trial where there exists a cause of action at common law, or one analogous thereto, for legal relief, where the amount in controversy exceeds twenty dollars. *Tull v. United States*, 481 U.S. 412, 417-18 (1987). Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[] at common law" and the Seventh Amendment's

guarantees are not implicated. We agree with the Ninth Circuit, which addressed this issue in the context of ERISA's preemption of state common-law causes of action:

> Congress surely can preempt a state cause of action, be it legal or equitable: This is the very nature of federal supremacy. Once Congress has chosen to preempt the state claim, it's free to give affected individuals a full federal claim, a claim providing only for remedies limited to equity, a damages claim only, or no claim at all. The Seventh Amendment, again, does not stand in the way.

Spinelli v. Gaughn, 12 F.3d 853, 858 (9th Cir. 1993) (footnote omitted). Accordingly, plaintiffs' Seventh Amendment claim must fail.

IV.

For the foregoing reasons, the judgment of the District Court is hereby AFFIRMED.

APPENDIX E — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO, EASTERN DIVISION FILED SEPTEMBER 7, 1994

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Case No. C2-93-580

Ada M. Martin, et al.,

Plaintiffs,

vs.

Telectronics Pacing Systems, Inc., et al.,

Defendants.

MEMORANDUM AND ORDER

Plaintiffs Ada and Harold Martin initiated this action on May 14, 1993, asserting numerous state law causes of action arising from Ada Martin's use of an implanted medical device known as the Guardian 4210 Cardioverter/Defibrillator System (the "Guardian 4210 System"). The defendants allegedly designed, manufactured, and supplied the Guardian 4210 System. The Guardian 4210 System consists of at least four parts: (1) a cardioverter/defibrillator (the "Defibrillator"); (2) model 040106 connectors (the "Connectors"); (3) model 033-572 sense/pace leads (the "Leads"); and (4) a model 033-415 adapter (the "Adapter"). This matter is now before the Court on Defendants' April 29, 1994 motion for summary judgment.

Appendix E

On March 31, 1992, doctors implanted the Guardian 4210 System in plaintiff Ada Martin. The parties agree that, at the time the system was implanted in Mrs. Martin, it was not approved by the Federal Food and Drug Administration (the "FDA") and was undergoing investigative study. The parties further agree that Ada Martin had consented to participate in the study of the Guardian 4210 System. On November 19, 1992, Ada Martin underwent a second surgical procedure during which physicians removed the Guardian 4210 System and replaced it with an alternate system. Pursuant to their initial complaint, plaintiffs alleged that the Connectors, the Leads, and the Defibrillator were defectively designed and manufactured and that Ada Martin was injured as a result of the defects and the resulting necessity of a second invasive surgical procedure. Mrs. Martin asserted five causes of action arising under Section 2307 of the Ohio Revised Code ("O.R.C."). Specifically, she asserted claims under O.R.C. §§ 2307.74, .75, .76, .77, and .78 related to the Defibrillator, the Connectors, and the Leads. Mr. Martin asserted a cause of action based upon Ohio common law for loss of consortium, services, and companionship. Plaintiffs sought $500,000 in damages. On August 19, 1993, Telectronics Pacing Systems, Inc. moved for summary judgment on plaintiffs' claims as they pertained to the Defibrillator and the Connectors on the ground that those claims were preempted by federal law, pursuant to 21 U.S.C. §360k(a), which states as follows:

> Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition

> to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

On December 14, 1993, this Court issued an Opinion and Order granting defendant Telectronics Pacing Systems, Inc.'s motion for partial summary judgment. In that Opinion and Order, the Court set forth its conclusion that plaintiffs' Ohio law causes of action related to the Defibrillator and the Connectors were preempted under 21 U.S.C. §360k(a). The Court concluded that the Ohio statutory and common law causes of action are requirements that are different from and in addition to the requirements applicable under the Medical Device Amendments of the Federal Drug Act. 21 U.S.C. §360k(a)(1). The Court also concluded that the state laws relate to the safety or effectiveness of the device. 21 U.S.C. §360k(a)(2). The Court dismissed plaintiffs' state law claims related to the Defibrillator and the Connectors. The Court did not consider plaintiffs' claims as they related to the Leads, because defendants had not moved for summary judgment on those claims.

Pursuant to an Order dated February 23, 1994, the Court granted plaintiffs' motion to file an amended complaint. In that amended complaint, plaintiffs assert the same causes of action as those that were raised in the initial complaint. Plaintiff Ada Martin asserts claims under §§ 2307.74, .75, .76, .77, and .78 with respect to the Leads and the Adapter. In addition, Mrs. Martin reasserts the claims related to the Defibrillator and the Connectors that the Court dismissed pursuant to the December

14, 1993 Opinion and Order. Plaintiff Harold Martin asserts a claim for loss of services, consortium, and companionship.

Defendants move for summary judgment on the ground that the Leads and the Adapter are components of the Guardian 4210 System and that the entire system is an investigational device under the Medical Device Amendments. Accordingly, defendants argue, 21 U.S.C. §360k(a) preempts plaintiffs' claims with respect to the Leads and the Adapter to the same extent as it preempts the claims related to the Defibrillator and the Connectors.

Plaintiffs concede that the Leads and the Adapter are components of the Guardian 4210 System and that the system is an investigational device under the Medical Device Amendments. Plaintiffs' Memorandum Contra, p.3. Plaintiffs argue, in essence, that the Courts conclusions in its December 14, 1993 opinion and Order are erroneous and that the Court should deny defendants' motion for summary judgment on plaintiffs' claims related to the Leads and the Adapter and reinstate plaintiffs' dismissed claims related to the Leads and the Defibrillator. Accordingly, the issue before the Court is identical to the one that the Court resolved in the December 14, 1993 Opinion and Order. The Court views plaintiffs' memorandum contra defendants' motion for summary judgment and defendants' reply memorandum as supplemental to those the Court considered in its earlier Opinion and Order. Because the issue before the Court is the same as that addressed in its December 14, 1993 Opinion and Order, the Court will consider in this Memorandum and Order whether plaintiffs have established that the Court erred in its earlier decision. Plaintiffs again argue that the Ohio statutes and common law upon which they base their claims are not the type of "requirements" that

are preempted under 21 U.S.C. §360k(a). Plaintiffs base their argument upon the language of 21 C.F.R. §808.1(d)(1), which states that the Medical Device Amendments do not preempt state or local requirements of general applicability where the state or local requirements relate to products in addition to medical devices. Plaintiffs contend that their causes of action are based upon state law requirements that are generally applicable to most products and are not restricted in applicability to medical devices. *see Mulligan v. Pfizer. Inc.*, Case No. C-1-92-672, U.S. Dist. LEXIS 4558 (S.D. Ohio April 14, 1994) The Court observes that the provision of the Code of Federal Regulations upon which plaintiffs rely also provides as follows:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act.

21 C.F.R. §808.1(b). Accordingly, plaintiffs may only base claims upon Section 2307 of the Ohio Revised Code and Ohio common law to the extent that their causes of action are based upon requirements of general applicability and the FDA has not established regulations regarding the manufacture, design, and use of the Guardian 4210 System.

Plaintiffs also rely extensively upon a recent decision from this District, *Mulligan, supra* (Spiegel, J.), and another from the District of Colorado, *Oja v. Howemedica , Inc.*, Case No. 93-C-858, slip op. (D.Colo. March 23, 1994). The *Mulligan* and *Oja* decisions were issued after this Court issued the December 14, 1993 Opinion and Order.

This Court does not take issue with any of the conclusions reached by the courts in those cases. The Court observes, however, that neither decision addresses the issue before the Court. The devices in question in *Mulligan* and *Oja* were not Class III devices, as is the Guardian 4210 System. The courts, therefore, did not determine whether the FDA's requirements for Class III investigational devices constitute "specific counterpart regulations," such that state or local requirements are preempted pursuant to 21 U.S.C. §360k(a) as interpreted by 21 C.F.R. §808.1(b). In its December 14, 1993 Opinion and Order, this Court concluded that the relevant state law causes of action are preempted. The *dicta* in the *Oja* decision suggests strongly that the court in that case concurs with this Court's conclusion:

> Class III devices are subject to formal and extensive pre-market approval requirements that qualify as "specific requirements applicable to a particular device" for preemption purposes. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 and n.3 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

Oja, supra, at p.7. While the Mulligan court did not discuss the distinctions between Class III and non-Class III devices, this Court finds nothing in the *Mulligan* decision that suggests that the conclusion therein applies equally to all classes of devices.

For the reasons set forth in this Court's December 14, 1993 Opinion and Order, together with those set forth herein, the Court concludes that all of the causes of action asserted by the plaintiffs

in their amended complaint are preempted by federal law. Accordingly, defendants' April 29, 1994 motion for summary judgment is hereby **GRANTED**. This case is **DISMISSED** in its entirety. The Clerk of this Court is directed to enter **JUDGMENT** in favor of the defendants.

IT IS SO ORDERED.

s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District Judge

Appendix E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

Case No: C2-93-580
Judge Beckwith
Magistrate Judge Abel

Ada M. Martin, et al.,

Plaintiffs,

v.

Telectronics Pacing Systems, Inc., et al.,

Defendants.

JUDGMENT IN A CIVIL CASE

[ ] Jury Verdict. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

[X] Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that pursuant to the September 7, 1994 Memorandum and Order by Judge Beckwith granting defendants' April 29, 1994 motion for summary judgment, this case is **DISMISSED. JUDGMENT** is entered in favor of the defendants.

Appendix E

September 7, 1994
Date

KENNETH J. MURPHY
Clerk

s/ Michael Carey
(By) Deputy Clerk
Michael Carey

APPENDIX F — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO, EASTERN DIVISION FILED DECEMBER 14, 1993

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Civil Action C-2-93-580

Judge Beckwith

Magistrate Judge Abel

Ada M. Martin, et al.,

Plaintiffs

v.

Telectronics Pacing Systems, Inc., et al.

Defendants

OPINION AND ORDER

Plaintiffs Ada and Harold Martin initiated this action in the Court of Common Pleas of Franklin County, Ohio on May 14, 1993, alleging numerous state-law causes of action arising from Ada Martin's use of certain medical devices designed and manufactured by Telectronics Pacing Systems, Inc. (hereinafter referred to as "Telectronics") or one of the Doe defendants named in the Complaint. On June 10, 1993, Telectronics removed

the action to this Court. This matter is presently before the Court for consideration of plaintiffs' motion to remand and cross motions for summary judgment.

Background

On March 31, 1992, doctors surgically implanted in plaintiff Ada Martin a cardioverter defibrillator (hereinafter referred to as the "Defibrillator"), Model 040-106 defibrillator leads (hereinafter referred to as the "Model 040-106 Leads"), and Model 033-572 leads (hereinafter referred to as the "Model 033-572 Leads" and together with the Model 040-106 Leads as the "Leads"), which were manufactured, designed, and/or supplied by electronics or one or more of the fifteen Doe defendants named in this action. The parties agree that the Defibrillator and the Model 040-106 Leads were not approved by the Federal Food and Drug Administration (hereinafter referred to as the "FDA") and were undergoing investigative study. The FDA had authorized the marketing of the Model 033-572 Leads. The parties further agree that Ada Martin had consented to participate in the study of the Defibrillator and the Model 040-106 Leads.

On November 19, 1992, Ada Martin underwent a second surgical procedure during which physicians removed the Defibrillator and the Leads and replaced them with another medical device. Ada Martin claims that the Defibrillator and the Leads were defective and that she was injured as a result of the defects and the resulting necessity of a second invasive surgical procedure. Among the alleged injuries are trauma to her body structure, permanent physical pain, anxiety, mental distress, loss of enjoyment of life, inability to perform ordinary activities, and physical impairment. Plaintiff claims that she will incur reasonable medical expenses and lost income into the

indefinite future. Plaintiff Harold Martin, Ada Martin's spouse, claims to have suffered loss of services, companionship, and consortium and alleges that he will suffer such loss into the indefinite future. Plaintiffs pray for damages in the amount of $500,000.00, together with interest and costs. Ada Martin asserts five causes of action arising under Section 2307 of the Ohio Revised Code ("O.R.C."). Specifically, she asserts that the Defibrillator and the Leads were defective in manufacture or construction in that they deviated from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units (O.R.C. §2307.74). She also alleges that the Defibrillator and the Leads were defective in design, because the risks associated with their design exceeded the benefits of that design (O.R.C. §2307.75). Pursuant to her third cause of action, plaintiff Ada Martin alleges that defendants provided inadequate warnings and instructions before and/or after the initial sale of the Defibrillator and the Leads (O.R.C. §3207.76). She further alleges that the Defibrillator and the Leads failed to conform to express representations of material facts concerning the character, quality, and/or safety of the products (O.R.C. §2307.77). Finally, plaintiff Ada Martin alleges that the defendants are liable for damages arising from her injuries as suppliers of defective products (O.R.C. §2307.78). Plaintiff Harold Martin asserts one cause of action based on Ohio common law pursuant to which he alleges the loss of his wife's services, companionship, and consortium.

The Motion to Remand

In its Notice of Removal, filed on June 10, 1993, defendant Telectronics cites two bases for this Court's exercise of jurisdiction over the subject matter of this action. First, defendant notes that diversity of citizenship exists between plaintiffs, who

are citizens of Ohio, and Telectronics, which is a citizen of Colorado for purposes of establishing diversity. Plaintiffs concede that diversity currently exists in this action; although, they argue that diversity may be destroyed by the identification of one or more of the Doe defendants. Telectronics also asserts federal question jurisdiction on the ground that plaintiffs' state law causes of action are preempted by federal law. Specifically, defendant asserts that the Medical Device Amendments to the Food, Drug and Cosmetic Act (hereinafter referred to together as the "Act") expressly preempt all state law remedies in the areas governed by the Act.

Plaintiffs move to remand on the ground that their state law causes of action are not preempted by the Act. They concede, however, that diversity is currently present. The Court notes that, for purposes of establishing diversity jurisdiction, the citizenship of Doe defendants is not considered. Section 1441 of Title 28, United States Code, provides, in pertinent part, as follows:

> (a) Except as otherwise provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending. For purposes of removal under this chapter, the citizenship of defendants sued under fictitious names shall be disregarded.

Clearly, defendant's removal of this action was permissible in spite of the fact that plaintiffs had named Doe defendants.

Appendix F

This Court may properly exercise jurisdiction over the subject matter of this dispute, the parties arguments concerning preemption notwithstanding. Plaintiffs' motion to remand is **DENIED.**

The Motions for Summary Judgment

While the Court need not resolve the parties' dispute concerning preemption in order to decide the plaintiffs' motion to remand this action, that dispute is also the focus of the parties' motions for summary judgment. On August 19, 1993, Telectronics moved for partial summary judgment. The basis for Telectronics' motion is that plaintiffs' claims related to the Defibrillator and the Model 040-106 Leads are preempted by federal law. By way of a response to defendant's motion, plaintiffs filed a motion for partial summary judgment, seeking a declaration that their state law claims are not preempted.

The Summary Judgment Standard

Rule 56 (c) provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." The purpose of the procedure is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried. *Lashlee v. Sumner,* 570 F.2d 107, 111 (6th Cir. 1978). Summary judgment, therefore, will not lie if the dispute about a material fact is genuine, "that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986) .

Appendix F

In a motion for summary judgment, the moving party bears the "burden of showing the absence of a genuine issue as to any material fact, and for these purposes, the [evidence submitted] must be viewed in the light most favorable to the opposing party." *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970); *accord, Adams v. Union Carbide Corp.*, 737 F.2d 1453, 1455-56 (6th Cir.), *cert. denied*, 469 U.S. 1062 (1984). The moving party is entitled to summary judgment "where it is quite clear what the truth is and where there are no unexplained gaps in documents submitted by the moving party pertinent to material issues of fact." *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 467 (1962); *accord, County of Oakland v. Berkley*, 742 F.2d 289, 297 (6th Cir. 1984); *Adickes*, 398 U.S. at 157-60; *Smith v. Hudson*, 600 F.2d 60, 65 (6th Cir.), *cert. dismissed*, 444 U.S. 986 (1979).

If the moving party meets its burden and if adequate time for discovery has been provided, the opposing party is required to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof as well. *Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986). The mere existence of a scintilla of evidence in support of the opposing party's claim will be insufficient; plaintiff "must set forth specific facts showing that there is a genuine issue for trial." *Davis v. Robbs*, 794 F.2d 1129, 1130 (6th Cir.), *cert. denied*, 479 U.S. 992 (1986) (emphasis in original).

Rule 56(e) provides as follows:

> When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere

> allegations or denials of his pleading, but his response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If he does not so respond, summary judgment, if appropriate, shall be entered against him.

Therefore, a party may not rest on the allegations contained in his pleadings to overcome a properly supported motion for summary judgment. *First National Bank v. Cities Service Co.*, 391 U.S. 253; 259 (1968) (footnote omitted).

Decision

Article VI of the United States Constitution provides that "the laws of the United States shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2. It is well-settled that "state law that conflicts with federal law is without effect." *Cippollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 120 L. Ed.2d 407, 422 (1992) (citing *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). "Consideration of issues arising under the Supremacy Clause start[s] with the assumption that the historic police powers of the States are] not to be superseded by . . . Federal Act unless that is] the clear and manifest purpose of Congress." *Id.* (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

"Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Id.* at 422-23 (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (internal quotation marks omitted)). Even in the

absence of an express congressional mandate, federal law may preempt state law with which it actually conflicts. *See Pacific Gas & Electric Co. v. Energy Resources Conservation and Development Commission*, 461 U.S. 190, 204 (1983). Preemption will also result when federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the states to supplement it. *Cippollone*, 120 L. Ed.2d at 423 (citing *Fidelity Federal Savings & Loan Association v. De la Cuesta*, 458 U.S. 141, 153 (1977) (internal quotation marks and citation omitted)).

When Congress has included a preemption provision in an enactment, the Court need not look beyond that provision to determine the preemptive scope of the enactment. *Cipollone*, 120 L. Ed.2d at 423 (citing *California Federal Savings & Loan Association v. Guerra*, 479 U.S. 272, 282 (1987) (opinion of Marshall, J.)). "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cippollone*, 120 L. Ed.2d at 423. Accordingly, when a preemption provision is included in the enactment, the Court need only "identify the domain expressly pre-empted" by that provision. *Id.* The Court must construe the provision in light of the presumption against the preemption of state police power regulations. *Id.* at 424.

The preemption provision in question in this action is found at 21 U.S.C. §360k(a), which states as follows:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The preemptive scope of 21 U.S.C. §360k(a) is extremely broad, even when examined in light of the presumption against preemption. Congress explicitly preempted any requirement relating to the safety or effectiveness of a medical device in addition to those set forth in the Act. Accordingly, the Court must determine whether the Ohio statutory causes of action asserted by plaintiff Ada Martin are requirements relating to the safety or effectiveness of the Defibrillator and the Model 040-106 Leads.

Plaintiff Ada Martin asserts five causes of action arising under O.R.C. chapter 2307. Section 2307.74, in conjunction with §2307.73, imposes liability upon the manufacturer of a defective product. Section 2307.74 identifies as a defective product one that deviates in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units. Section 2307.75 establishes liability against the manufacturer of a product that is defective in design or formulation. Section 2307.76 provides that a manufacturer may be liable for a defect resulting from inadequate warning and instruction. Similarly, §2307.77 establishes the liability of a manufacturer whose product does not conform to a representation made by that manufacturer.

Appendix F

Each of the provisions contained in O.R.C. §§2307.74-.77 relates to the safety or effectiveness of a product. Plaintiffs argue that those provisions are not requirements and, therefore, are not preempted by the Act. The Supreme Court has stated, however, that the obligation to pay damages is itself a method of governing conduct and, thus, a requirement. *Cippollone*, 120 L. Ed.2d at 425-26. The Court noted that tort damage actions "are premised on the existence of a legal duty and it is difficult to say that such actions do not impose requirements or prohibitions." *Id.* at 426 (internal quotation marks and citation omitted). The Court concludes, therefore, that plaintiff Ada Martin's first four causes of action are preempted under 21 U.S.C. §360k(a).

Pursuant to her fifth cause of action, plaintiff Ada Martin attempts to impose liability upon defendant as a supplier of the Defibrillator and the Leads under O.R.C. §2307.78. Plaintiff incorporates the allegations of her four previous causes of action. Inasmuch as her plaintiff's fifth cause of action also relates to the safety and effectiveness of the Defibrillator, the Court concludes that it is preempted by the Act.

This Court's conclusions are consistent with those reached by the Seventh Circuit Court of Appeals in *Slater v. Optical Radiation Corporation*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992). The *Slater* court determined that 21 U.S.C. §360k(a) dictated the preemption of state law tort claims related to the design of an intraocular lens that was, like the Defibrillator and the Model 040-106 Leads, an investigational device for purposes of the application of the Act. The court concluded that the plaintiff's claims were preempted but noted that the preemptive scope of the Act is limited. *Id.* at 1334. The court stated, for example, that causes of action related to

improper implantation or removal of the device, contamination of the device by bacteria or fungi, or failure to obtain the patient's informed consent would not be preempted. *Id.*

Plaintiffs argue that the *Slater* case is distinguishable from this action. While plaintiffs concede the similarity between some of their claims and those asserted by the plaintiff in *Slater*, they argue that their claims relating to defendant's alleged deviation from its own specifications are unlike any raised in *Slater* and are not preempted by the Act; The Court notes that the *Slater* court did not attempt to define the universe of preempted claims. Plaintiffs' claim of deviation from specifications undeniably relates to the safety and effectiveness of the Defibrillator and the Leads, and the Court determines that plaintiffs cannot maintain that cause of action in the face of 21 U.S.C. §360k(a).

Plaintiff Harold Martin asserts only one claim. He alleges that, as a result of defendant's actions as alleged in the first five causes of action, he has lost his wife's services, companionship, and consortium. Plaintiff Harold Martin may only recover damages for his loss if defendant intentionally or negligently injured his wife, thereby causing an injury to him. *See,e.g., Bowen v. Kil-Kare. Inc.*, 63 Ohio St.3d 84, 90 (1992). Harold Martin makes no allegations, however, apart from those asserted by his wife. The Court has determined that all of Ada Martin's allegations relate to the safety or effectiveness of the Defibrillator and the Leads and that the claims based upon those allegations are preempted pursuant to 21 U.S.C. §360k(a). The Court concludes that Harold Martin's common law cause of action also is preempted as attempting to impose upon defendant the same requirements relating to safety and effectiveness as do the claims asserted by his wife.

Appendix F

Plaintiffs argue that Congress could not have intended to leave injured persons without a remedy. The Court notes that some remedies are available under the Act itself. The Court also notes, however, to the extent that some injuries may go unredressed as a result of preemption, Congress requires that a manufacturer of an investigational device obtain the informed consent of any participant in the investigation of the device. 21 U.S.C. §360j(g)(3)(D). Failure to obtain such consent is a violation of the Act. Accordingly, an injured party has not been subjected to a risk without prior knowledge that the device in question was not, and may never be, thoroughly tested and approved by the FDA.

Conclusion

For the foregoing reasons, plaintiffs' motion to remand is hereby **DENIED**. Plaintiffs' motion for partial summary judgment is also hereby **DENIED**. Defendant Telectronics Pacing Systems, Inc.'s motion for partial summary judgment is hereby **GRANTED**. All of plaintiffs' claims against defendant Telectronics relating to the Defibrillator and the Model 040-106 Leads are dismissed. Because defendant Telectronics has not sought summary judgment with respect to plaintiffs' claims as they relate to the Model 033-572 Leads, this action will proceed on those claims only.

IT IS SO ORDERED.

s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District Judge

APPENDIX G — RELEVANT PROVISIONS OF THE CONSTITUTION OF THE UNITED STATES, STATUTES AND REGULATIONS

UNITED STATES CONSTITUTION

ARTICLE I, SECTION 8

* * *

To regulate commerce with foreign Nations, and among the several States, and with the Indian Tribes. . . .

ARTICLE VI

* * *

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

* * *

AMENDMENT VII

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved,

and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

(Effective 1791)

AMENDMENT IX

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

(Effective 1791)

AMENDMENT X

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

(Effective 1791)

Appendix G

FEDERAL STATUTES AND REGULATIONS

21 U.S.C. § 360h(d)

Effect on Other Liability

Compliance with an order [requiring a manufacturer to repair, replace, or provide reimbursement for expenses relating to an unsafe device] issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 U.S.C. § 360j

§ 360j. General provisions respecting control of devices intended for human use

* * *

(g) Exemption for devices for investigational use

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for

human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribed procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i, or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such from and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and

maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require,

as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption —

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing —

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if —

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to

such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedure prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 360f of this title) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

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(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

* * *

Appendix G

21 U.S.C. § 360k

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if —

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

* * *

21 C.F.R. § 808.1(d)

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they

are not "requirements applicable to a device" within the meaning of section 521 (a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and ' the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices . . .

OHIO REVISED CODE

§ 2307.71 Definitions.

As used in sections 2307.71 to 2307.80 of the Revised Code:

(A) "Claimant" means other of the following:

(1) A person who asserts a product liability claim or on whose behalf such a claim is asserted;

(2) If a product liability claim is asserted on behalf of the surviving spouse, children,

parents, or other next of kin of a decedent or on behalf of the estate of a decedent, whether as a claim in a wrongful death action under Chapter 2125, of the Revised Code or as a survivorship claim, whichever of the following is appropriate:

(a) The decedent, if the reference is to the person who allegedly sustained harm or economic loss for which, or in connection with which, compensatory damages or punitive or exemplary damages are sought to be recovered;

(b) The personal representative of the decedent or the estate of the decedent, if the reference is to the person who is asserting or has asserted the product liability claim.

(B) "Economic loss" means direct, incidental, or consequential pecuniary loss including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product. Harm is not "economic loss."

(C) "Environment" means navigable waters, surface water, ground water, drinking water supplies, land surface, subsurface strata, and air.

(D) "Ethical drug" means a prescription drug that is prescribed or dispensed by a

physician or any other person who is legally authorized to prescribe or dispense a prescription drug.

(E) "Ethical medical device" means a medical device that is prescribed, dispensed, or implanted by a physician or any other person who is legally authorized to prescribe, dispense, or implant a medical device and that is regulated under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C 301-392, as amended.

(F) "Foreseeable risk" means a risk of harm that satisfies both of the following:

(1) It is associated with an intended or reasonably foreseeable use, modification, or alteration of a product in question;

(2) It is a risk that the manufacturer in question should recognize while exercising both of the following:

(a) The attention, perception, memory, knowledge, and intelligence that a reasonable manufacturer should possess;

(b) Any superior attention, perception, memory, knowledge, or intelligence that the manufacturer in question possesses.

(G) "Harm" means death, physical injury

to person, serious emotional distress, or physical damage to property other than the product in question. Economic loss is not "harm."

(H) "Hazardous or toxic substances" include, but are not limited to, hazardous waste as defined in section 3734.01 of the Revised Code, hazardous waste as specified in the rules of the director of environmental protection pursuant to division (A) of section 3734.12 of the Revised Code, hazardous substances as defined in section 3716.01 of the Revised Code, and hazardous substances, pollutants, and contaminants as defined in or by regulations adopted pursuant to the "Comprehensive Environmental Response, Compensation, and Liability Act of 1980," 94 Stat. 2767, 42 U.S.C. 9601, as amended.

(I) "Manufacturer" means a person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product.

(J) "Person" has the same meaning as in division (C) of section 1.59 of the Revised Code and also includes governmental entities.

(K) "Physician" means a person who is licensed to practice medicine and surgery or

osteopathic medicine and surgery by the state medical board.

(L)(1) "Product" means, subject to division (L)(2) of this section, any object, substance, mixture, or raw material that constitutes tangible personal property and that satisfies all of the following:

(a) It is capable of delivery itself, or as an assembled whole in a mixed or combined state, or as a component or ingredient;

(b) It is produced, manufactured, or supplied for introduction into trade or commerce;

(c) It is intended for sale or lease to persons for commercial or personal use.

(2) "Product" does not include human tissue, blood, or organs.

(M) "Product liability claim" means a claim that is asserted in a civil action and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:

(1) The design, formulation, production,

construction, creation, assembly, rebuilding, testing, or marketing of that product;

(2) Any warning or instruction, or lack of warning or instruction, associated with that product;

(3) Any failure of that product to conform to any relevant representation or warranty.

(N) "Representation" means an express representation of a material fact concerning the character, quality, or safety of a product.

(O)(1) "Supplier" means, subject to division (O)(1) of this section, either of the following:

(a) A person that, in the course of a business conducted for the purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce;

(b) A person that, in the course of a business conducted for the purpose, installs, repairs, or maintains any aspect of a product that allegedly causes harm.

(2) "Supplier" does not include any of the following:

(a) A manufacturer;

(b) A seller of real property;

(c) A provider of professional services who, incidental to a professional transaction the essence of which is the furnishing of judgment, skill, or services, sells or uses a product;

(d) Any person who acts only in a financial capacity with respect to the sale of a product, or who leases a product under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

(P) "Unavoidably unsafe" means that, in the state of technical, scientific, and medical knowledge at the time a product in question left the control of its manufacturer, an aspect of that product was incapable of being made safe.

§ 2307.72 Damages recoverable on product liability claim; environmental damage.

(A) Any recovery of compensatory damages based on a product liability claim is subject to sections 2307.71 to 2307.79 of the Revised Code.

(B) Any recovery of punitive or exemplary damages in connection with a product liability claim is subject to sections 2307.71 to 2307.80 of the Revised Code.

(C) Any recovery of compensatory damages for economic loss based on a claim that is asserted in a civil action, other than a product liability claim, is not subject to sections 2307.71 to 2307.79 of the Revised Code, but may occur under the common law of this state or other applicable sections of the Revised Code.

(D)(1) Sections 2307.71 to 2307.80 of the Revised Code do not supersede, modify, or otherwise affect any statute, regulation, or rule of this state or of the United States, or the common law of this sate or of the United States, that relates to liability in compensatory damages or punitive or exemplary damages for injury, death, or loss to person or property, or to relief in the form of the abatement of a nuisance, civil penalties, cleanup costs, cost recovery, an injunction or temporary restraining order, or restitution, that arises, in whole or in part, from contamination or pollution of the environment or a threat of contamination or pollution of the environment, including contamination or pollution or a threat of contamination or pollution from hazardous or toxic substances.

(2) Consistent with the Rules of Civil Procedure, in the same civil action against the same defendant or different defendants, a claimant may assert both of the following:

(a) A product liability claim, including a claim for the recovery of punitive or exemplary damages in connection with a product liability claim;

(b) A claim for the recovery of compensatory damages or punitive or exemplary damages for injury, death, or loss to person or property, or for relief in the form of the abatement of a nuisance, civil penalties, cleanup costs, cost recovery, an injunction or temporary restraining order, or restitution, that arises, in whole or in part, from contamination or pollution of the environment or a threat of contamination or pollution of the environment, including contamination or pollution or a threat of contamination or pollution from hazardous or toxic substances.

§ 2307.3 When manufacturer is liable for compensatory damages; evidence of defect.

(A) A manufacturer is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, both of the following:

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(1) Subject to division (B) of this section, the product in question was defective in manufacture or construction as described in section 2307.74 of the Revised Code, was defective in design or formulation as described in section 2307.75 of the Revised Code, was defective due to inadequate warning or instruction as described in section 2307.76 of the Revised Code, or was defective because it did not conform to a representation made by its manufacturer as described in section 2307.77 of the Revised Code;

(2) A defective aspect of the product in question as described in division (A)(l) of this section was a proximate cause of harm for which the claimant seeks to recover compensatory damages.

(B) If a claimant is unable because a product in question was destroyed to establish by direct evidence that the product in question was defective or if a claimant otherwise is unable to establish by direct evidence that a product in question was defective, then, consistent with the Rules of Evidence, it shall be sufficient for the claimant to present circumstantial or other competent evidence that establishes, by a preponderance of the evidence, that the product in question was defective in any one of the four respects specified in division (A)(l)of this section.

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§ 2307.74 When product is defective in manufacture or construction.

A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

§ 2307.75 When product is defective in design or formulation.

(A) Subject to divisions (D), (E), and (F) of this section, a product is defective in design or formulation if either of the following applies:

(1) When it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section;

(2) It is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

(B) The foreseeable risks associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:

(1) The nature and magnitude of the risks of harm associated with that design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;

(2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;

(3) The likelihood that that design or formulation would cause harm in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;

(4) The extent to which that design or formulation conformed to any applicable public or private product standard that was in effect when the product left the control of its manufacturer.

(C) The benefits associated with the design or formulation of a product shall be

determined by considering factors including, but not limited to, the following:

(1) The intended or actual utility of the product, including any performance or safety advantages associated with that design or formulation;

(2) The technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation;

(3) The nature and magnitude of any foreseeable risks associated with such an alternative design or formulation.

(D) An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

(E) A product is not defective in design or formulation if the harm for which the claimant seeks to recover compensatory damages was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially

compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.

(F) A product is not defective in design or formulation if, at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product, unless the manufacturer acted unreasonably in introducing the product into trade or commerce.

§ 2307.76 When product is defective due to inadequate warning or instruction.

(A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:

(1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have

known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory

damages and in light of the likely seriousness of that harm.

(B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

(C) An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

§ 2307.77 Conformance to representa-tion.

A product is defective if it did not conform when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

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§ 2307.78 When a supplier is liable for compensatory damages.

(A) Subject to division (B) of this section, a supplier is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, that either of the following applies:

(1) The supplier in question was negligent and that negligence was a proximate cause of harm for which the claimant seeks to recover compensatory damages;

(2) The product in question did not conform, when it left the control of the supplier in question, to a representation made by that supplier, and that representation and the failure to conform to it were a proximate cause of harm for which the claimant seeks to recover compensatory damages. A supplier is subject to liability for such a representation and the failure to conform to it even though the supplier did not act fraudulently, recklessly, or negligently in making the representation.

(B) A supplier of a product is subject to liability for compensatory damages based on a product liability claim under sections 2307.71 to 2307.77 of the Revised Code, as

if it were the manufacturer of that product, if the manufacturer of that product is or would be subject to liability for compensatory damages based on a product liability claim under sections 2307.71 to 2307.77 of the Revised Code and any of the following supplies:

(1) The manufacturer of that product is not subject to judicial process in this state;

(2) The claimant will be unable to enforce a judgment against the manufacturer of that product due to actual or asserted insolvency of the manufacturer;

(3) The supplier in question owns or, when it supplied that product, owned, in whole or in part, the manufacturer of that product;

(4) The supplier in question is owned or, when it supplied that product, was owned, in whole or in part, by the manufacturer of that product;

(5) The supplier in question created or furnished a manufacturer with the design or formulation that was used to produce, create, make, construct, assemble, or rebuild that product or a component of that product;

(6) The supplier in question altered,

modified, or failed to maintain that product after it came into the possession of, and before it left the possession of, the supplier in question, and the alteration, modification, or failure to maintain that product rendered it defective;

(7) The supplier in question marketed that product under its own label or trade name;

(8) The supplier in question failed to respond timely and reasonably to a written request by or on behalf of the claimant to disclose to the claimant the name and address of the manufacturer of that product.

§ 2307.79 Compensatory damages for economic loss.

(A) If a claimant is entitled to recover compensatory damages for harm from a manufacturer in accordance with section 2307.73 of the Revised Code or from a supplier in accordance with division (B) of section 2307.78 of the Revised Code, the claimant may recover from the manufacturer or supplier in question, in that action, compensatory damages for any economic loss that proximately resulted from the defective aspect of the product in question.

(B) If a claimant is entitled to recover compensatory damages for harm from a

supplier in accordance with division (A) of section 2307.78 of the Revised Code, the claimant may recover from the supplier in question, in that action, compensatory damages for any economic loss that proximately resulted from the negligence of that supplier or from the representation made by that supplier and the failure of the product in question to conform to that representation.

§ 2307.80 Punitive or exemplary damages.

(A) Subject to division (C) of this section, punitive or exemplary damages shall not be awarded against a manufacturer or supplier in question in connection with a product liability claim unless the claimant establishes, by clear and convincing evidence, that harm for which he is entitled to recover compensatory damages in accordance with section 2307.73 or 2307.78 of the Revised Code was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question. The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product.

(B) Whether the trier of fact is a jury or the court, if the trier of fact determines that

a manufacturer or supplier in question is liable for punitive or exemplary damages in connection with a product liability claim, the amount of those damages shall be determined by the court. In determining the amount of punitive or exemplary damages, the court shall consider factors including, but not limited to, the following:

(1) The likelihood that serious harm would arise from the misconduct of the manufacturer or supplier in question;

(2) The degree of the awareness of the manufacturer or supplier in question of that likelihood;

(3) The profitability of the misconduct to the manufacturer or supplier in question;

(4) The duration of the misconduct and any concealment of it by the manufacturer or supplier in question;

(5) The attitude and conduct of the manufacturer or supplier in question upon the discovery of the misconduct and whether the misconduct ha terminated;

(6) The financial condition of the manufacture or supplier in question;

(7) The total effect of other punishment

imposed or likely to be imposed upon the manufacturer or supplier in question as a result of the misconduct including awards of punitive or exemplary damage to persons similarly situated to the claimant and the severity of criminal penalties to which the manufacturer or supplier in question has been or is likely to be subjected.

(C) If a claimant alleges in a product liability claim that a drug caused harm to him, the manufacturer of the drug shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug that allegedly caused the harm was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. 301-392, as amended, or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. 201-300cc-15, as amended, unless it is established, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type. For

purposes of this division, "drug has the meaning given to that term In section 1201(g)(1) of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C 301-392, as amended.

No. 96-1749

Supreme Court, U.S.
FILED
JUN 2 1997

In The

Supreme Court of the United States

October Term, 1996

ADA M. MARTIN and HAROLD L. MARTIN,

Petitioners,

vs.

TELECTRONICS PACING SYSTEMS, INC.; TPLC, INC. d/b/a Telectronics Pacing Systems; TELECTRONICS PTY LIMITED,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

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RULE 29.6 STATEMENT

Respondents Telectronics Pacing Systems, Inc., TPLC, Inc. d/b/a Telectronics Pacing Systems, and Telectronics PTY Limited, are related corporations that are each beneficially owned by Pacific Dunlop, Ltd. as the ultimate parent corporation. A list of all Pacific Dunlop, Ltd. subsidiaries is submitted as a Lodging Appendix.

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COUNTERSTATEMENT OF THE CASE

Respondents generally accept as accurate the Statement of the Case included in the Petition for Writ of Certiorari. Pursuant to Sup. Ct. R. 15.2, however, Respondents address the following perceived misstatement of fact included in Petitioners' brief.

This case involves the question of federal preemption under the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act. The underlying lawsuit is a product liability action in which Petitioners claim to have been injured by a medical device, known as the Telectronics Guardian 4210 Cardioverter/Defibrillator (the "Guardian System"), prescribed by a doctor to treat Petitioner Ada Martin's heart condition. Petitioners accurately describe the Guardian System as a device "which provides combined functions of a defibrillator with a cardioverter and a pacemaker." Pet. at 2. Petitioners concede that "[t]he Guardian 4210 System, *including all four component parts*, is a medical device currently subject to investigational testing pursuant to the Medical Device Amendments to the 1938 Food, Drug and Cosmetic Act." Pet. at 2-3 (emphasis added). Petitioners further concede that "the product *system* had secured 'investigational device exemption ["IDE"]' " under the MDA. *Id.* at 3 (emphasis added).

Notwithstanding these candid admissions, Petitioners contend that "two of the four components of the 4210 system . . . were used *in the system* under a Section 510(k) exemption and not through the IDE exemption." *Id.* (emphasis added). This contention is erroneous and must be rejected by this Court for several reasons.

First, Petitioners' statement reveals a fundamental misunderstanding of the statutory and regulatory provisions governing medical devices. Respondents readily acknowledge that, at different times and in different contexts, the Food and Drug Administration ("FDA") authorized for market distribution two discrete components of the Guardian System upon a finding of "substantial equivalence" under section 510(k) of the MDA. This is not to say, however, that the FDA's finding of "substantial equivalence" authorized Respondents to

use these components in an experimental or investigational context such as the one at issue here. *See, e.g., Oja v. Howmedica, Inc.*, 111 F.3d 782, 1997 U.S. App. LEXIS 7175 (10th Cir. 1997) (describing FDA authorization to conduct clinical investigation of a device "in an experimental context" that, in a different configuration, had been authorized for market distribution under section 510(k)).

By definition, an investigational device is one for which there is insufficient information for the FDA to make a determination as to its safety and effectiveness. *See generally* 21 U.S.C. § 360j(g); 21 C.F.R. § 812.1 *et seq.* (generally describing purpose of investigational device exemption). In other words, the proposed device is new. By contrast, a finding of substantial equivalence presupposes that the device "has the same intended use" and "the same technological characteristics" as a "predicate device" which is already on the market. *See* 21 C.F.R. § 807.100(b) (criteria for determining substantial equivalency). Where, as here, the device is part of a unique configuration comprised of several components which, taken together, form a completely new device, there is no "predicate device" with the same intended use and thus no basis for a finding of substantial equivalence. Accordingly, while some of the Guardian System's component parts may have been governed by section 510(k) regulations when used in other contexts, there is no doubt that they were governed by the investigational device exemption regulations in the only context relevant to these proceedings.

Second, Petitioners' statement is an impermissible re-argument of facts. At trial, Respondents argued that Petitioners' claims were preempted by federal regulations governing investigational devices. *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997). In the alternative, Respondents noted that two components of the Guardian System had been separately reviewed by the FDA under federal regulations governing "substantially equivalent" devices and submitted that preemption would be appropriate under those regulations as well. *Id.* The trial court accepted as fact that the components were part of the investigational device at issue, and appropriately proceeded to analyze the preemption question in view of the investigational device regulations. *Id.* at 1098. Significantly,

Petitioners never challenged, and conceded at every turn, the factual premise underlying the trial court's analysis. *Id.* at 1097-1098. The appellate court declined Petitioners' invitation to re-examine facts which Petitioners had conceded at trial, *id.* at 1098, and this Court should similarly reject Petitioners' attempt to reargue or assert new and different facts on appeal.

Third, Petitioners' attempt to refashion its case on appeal should be recognized and rejected for what it is: an undisguised attempt to bootstrap onto this Court's recent decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). In *Lohr*, this Court concluded in a five-to-four plurality decision that the MDA did not preempt certain common law claims against the manufacturer of a "substantially equivalent" device. Obviously, Petitioners recognize that characterizing the investigational device at issue here as a "substantially equivalent" device would allow them to take advantage of the *Lohr* decision. Accordingly, Petitioners have devoted substantial time and effort to "reclassifying" the device at issue both during the appeal after remand and again in their petition for a writ of certiorari

Petitioners explain their failure to raise this issue prior to *Lohr* by stating that it was "impossible for attorneys as well as lower courts to anticipate what the United States Supreme Court will find relevant or important." Pet. at 9. This argument is disingenuous. At the time the preemption issue was presented to the trial court, and certainly by the time the issue was first argued on appeal, federal and state courts at both the trial and appellate levels had already begun to draw sharp distinctions between "substantially equivalent" devices and other medical devices for purposes of conducting a preemption analysis under the MDA. The distinction has always been important. Respondents recognized it and argued in the alternative. Petitioners did neither. Accordingly, notwithstanding Petitioners' lament that the appellate court "chose to assert the pre-*Lohr* arguments of counsel as the true facts of the case," it is beyond cavil that the *Lohr* decision did not and cannot alter the facts established and conceded by Petitioners below. The device at issue here is an investigational device, governed by the investigational device provisions of the MDA.

For all of the foregoing reasons, Respondents respectfully disagree with Petitioners' statement that federal statutes and regulations governing "substantially equivalent" devices are applicable to the Guardian System or to any of its component parts.

REASONS FOR DENYING THE WRIT

I. THIS DECISION BELOW DOES NOT CONFLICT WITH DECISIONS OF OTHER COURTS OF APPEAL AND INTERPRETS THE STATUTE, 21 U.S.C. § 360k(a) CONSISTENTLY WITH CONGRESSIONAL INTENT AS INTERPRETED BY THIS COURT IN *MEDTRONIC, INC. v. LOHR*, 116 S. Ct. 2240 (1996) [RESTATED].

Petitioners assert that their petition should be granted because the Sixth Circuit Court of Appeals "improperly interpreted and improperly applied" this Court's decision in *Medtronic, Inc. v. Lohr*. Pet. at 6. Petitioners also argue that a writ for certiorari should be granted because the Sixth Circuit's decision conflicts with decisions from other federal appellate courts. *Id.* Respondents address each argument in turn.

A. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*, this Court addressed for the first time the preemptive scope of the MDA. At the outset, the Court reiterated the well-established principle that " '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case," *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2250 (1996) (quoting *Retail Clerks International Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963)), and noted that "any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of congressional purpose.' " *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 n.27 (1992)). Of course, this understanding starts with "the language of the pre-emption statute and the 'statutory framework' surrounding it." *Id.* at 2251 (quoting *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring)). However, the *Lohr* Court also observed that "the 'structure and purpose of the statute as a whole,'

as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers and the law," is relevant to a principled preemption analysis. *Id.* (quoting *Gade*, 505 U.S. at 98).

1. The Language of the MDA

Turning to the first step in this analytical process, the Court looked to the express preemption clause of the MDA which provides, in pertinent part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Court acknowledged that the above-quoted language is sufficiently clear to reveal that Congress intended "the MDA to pre-empt at least some state law. . . ." *Lohr*, 116 S. Ct. at 2250. Five justices, however, found that the MDA's preemption language was too ambiguous to indicate exactly what state laws should be preempted and in what circumstances. *See id.* at 2255 ("the language of that section is not entirely clear") (Stevens, J.); *id.* at 2260 (describing the MDA's express preemption provision as "highly ambiguous") (Breyer, J., concurring in part and concurring in the judgment). Accordingly, the Court looked to "the structure and purpose of the statute as a whole" for guidance in assessing the MDA's intended preemptive scope.

2. The Structure and Purpose of the MDA

Congress enacted the MDA in response to rapid growth in the use of medical devices to treat a variety of diseases and conditions, coupled with growing concern "about the increasingly severe injuries that resulted from the failure of such devices." *Lohr*, 116 S. Ct. at 2246. Prior to that time, there was no meaningful oversight of the medical device industry at any level, and no process comparable to that provided for pharmaceuticals whereby manufacturers were required to demonstrate the safety and efficacy of their products before distributing them in the market. *See id.*

When it enacted the MDA, Congress intended to change this status quo. The goals of the legislation are set forth in the text of the statute and in its legislative history. Of primary importance was the desire of Congress to improve "the safety and effectiveness of devices intended for human use." *Lohr*, 116 S. Ct. at 2253 (citing 90 Stat. 539). A second clearly articulated goal was to "encourage . . . research and development" of new, potentially lifesaving or life-enhancing medical device technology. *Id.* at 2253 & n. 12; S. Rep. No. 33, 94th Cong. 2d Sess. 1, 2 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071.

To accomplish these goals, the MDA first requires the FDA to classify every medical device into one of three categories based on the risk they pose to the public. *See* 21 U.S.C. § 360c(a)(1); *Lohr*, 116 S. Ct. at 2246. Devices intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or which present "a potential unreasonable risk of illness or injury," are designated as Class III. *Id.* § 360c(a)(1)(C). Congress required all Class III device manufacturers to prove to the FDA that their products were reasonably safe and effective before they could begin distribution in the market. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e. This *a priori* review and approval requirement, "known as the 'premarket approval,' or 'PMA' process, is a rigorous one." *Lohr*, 116 S. Ct. at 2246-47. To obtain PMA approval, "[m]anufacturers must submit detailed information regarding the safety and efficacy of their devices." *Id.* at 2247. The FDA reviews this

information, "spending an average of 1,200 hours on each submission." *Id.*

Congress realized, however, when it enacted the MDA, "that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices." *Id.* In other words, Congress knew the FDA could not expose hundreds or thousands of existing medical devices to PMA scrutiny overnight, and at the same time, could not bring the medical device industry to a crashing halt pending full implementation of the MDA's substantive provisions.

The solution, embodied in the MDA, was to allow already existing devices "to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA." *Id.* (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1)). In addition, to prevent manufacturers of these "grandfathered" devices from "monopolizing the market while new devices clear the PMA hurdle," Congress also permitted post-enactment devices to enter the market without FDA approval so long as they were "substantially equivalent" to their pre-enactment predecessors. *See id.; see also* 21 U.S.C. § 360e(b)(1)(B).

The device at issue in *Lohr* was just such a "substantially equivalent" device. The *Lohr* Court noted that the process for determining whether a device was substantially equivalent to a pre-enactment device "is by no means comparable to the PMA process," and that unlike PMA approval, a finding of substantial equivalence does not establish that the device is reasonably safe and effective. *See Lohr*, 116 S. Ct. at 2254; *see also* 21 C.F.R. § 807.97 (finding of substantial equivalence "does not in any way denote official approval of the device"). As the Court observed,

> [S]ubstantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less

> effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.

Lohr, 116 S. Ct. at 2254 (citation omitted).

3. Applying the MDA's Preemption Provision

Having thus reviewed the language, the structure and the purpose of the MDA, the *Lohr* Court turned its attention to determining whether the particular state laws in that case were preempted by the MDA. Both the plurality and dissenting opinions undertook a careful comparison of the state law claims and the federal regulations applicable to Lohr's "substantially equivalent" device. Ultimately, a plurality of the Court concluded that the applicable federal laws did not preempt the state common law claims at issue. The underlying rationale for this conclusion, however, is not entirely clear, and no single approach to determining the MDA's preemptive scope commanded a majority.

Without belaboring the areas of agreement and disagreement found in the plurality, concurring and dissenting opinions, Respondent submits that the following summary fairly characterizes the Court's position:

(a) All nine justices apparently agreed that common law claims can impose "requirements" under color of state law. *See, e.g., Lohr*, 116 S. Ct. at 2259 ("it will be rare indeed [but apparently not impossible] for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.' ") (Stevens, J.); *id.* at 2260 ("insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.") (Breyer, J., concurring in part and concurring in the judgment); *id.* at 2263 ("If § 360k's language is given its ordinary meaning, it clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the [MDA].") (O'Connor, J., concurring in part and dissenting in part). Five justices therefore concluded that the word

"requirement" in the MDA's express preemption provision was indicative of Congress' intent to preempt common law claims, at least in some circumstances. *Id.* at 2262 (Justices Scalia and Thomas and Chief Justice Rehnquist joined in Justice O'Connor's opinion); *id.* at 2259 ("I basically agree with Justice O'Connor's discussion of this point and with her conclusion.") (Breyer, J. concurring). The remaining four justices disagreed, not on the basis that common law claims do not impose requirements, but because these are not the type of requirements Congress intended the MDA to preempt. *See id.* at 2258 ("These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common law duty, but rather because their generality leaves them outside the category of requirements § 360k envisioned to be 'with respect to' specific devices such as pacemakers.") (Stevens, J.).

(b) The Court was unanimous in the view that state common law claims would not be preempted to the extent the requirements imposed by such claims were the same as those applicable under the MDA. *Id.* at 2255-2256 (Stevens, J.); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). This situation might typically arise in the context of a negligence *per se* claim where state common law incorporates as the appropriate standard of care the same requirements applicable under the MDA. Thus, even though requirements are imposed at both the state and the federal level, there is no preemption because the state-law requirements are identical to, instead of "different from, or in addition to" the relevant federal requirements.

(c) The Court was unanimous in its view that Lohr's design defect claim was not preempted. *Id.* at 2254-55 (Stevens, J.); *id.* at 2263-64 (O'Connor, J., concurring in part and dissenting in part). Without reaching agreement on whether a common law design defect claim could impose a design-related requirement at the state level, all nine justices observed that the regulations governing "substantially equivalent" devices did not impose design-related requirements at the federal level. Absent a federal design requirement, there was nothing for Lohr's state law claims to be "different from, or in addition to," and thus no basis for preemption.

(d) With respect to Lohr's manufacturing and failure to warn claims, all nine justices apparently agreed that the device at issue was subject to federal requirements imposed under the MDA. *See id.* at 2258 (acknowledging the existence of federal labeling and manufacturing requirements applicable to medical devices generally); *id.* at 2261 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). Four justices concluded that the existence of federal requirements applicable to the device was sufficient to trigger preemption under the MDA. *Id.* at 2264 ("These extensive federal manufacturing and labeling requirements are certainly applicable to the device manufactured by Medtronic [and] [s]ection 360k(a) requires no more specificity than that for pre-emption of state common-law claims.") (O'Connor, J., concurring in part and dissenting in part). The five justices comprising the plurality disagreed, not on the basis that there were no federal requirements, but because these were not the type of requirements Congress intended to have a preemptive effect. *Id.* at 2258 (MDA was not designed to protect "generic" federal requirements "from potentially contradictory state requirements.") (Stevens, J.); *id.* at 2261 (FDA "does not intend [applicable federal] requirements to pre-empt the state requirements at issue here.") (Breyer, J., concurring in part and concurring in the judgment).

(e) The five justices who believed that the federal requirements applicable to "substantially equivalent" devices were not intended to have a preemptive effect relied heavily on interpretative regulations promulgated by the FDA. *See, e.g., id.* at 2255-58 (discussing FDA's interpretive regulations with approval) (Stevens, J.); *id.* at 2260-61 (same) (Breyer, J., concurring in part and concurring in the judgment). Those regulations state that:

> State . . . requirements are preempted only when . . . there are . . . specific [federal] requirements applicable to a particular device . . . thereby making any existing divergent State . . . requirements applicable to the device different from, or in addition to, the specific [federal] requirements.

Id. at 2260-61 (paraphrasing 21 C.F.R. § 808.1(d)).

The FDA's interpretive view persuaded the *Lohr* plurality that federal requirements imposed under the MDA must be device-specific to preempt state law. The plurality concluded that the "general" requirements applicable to "substantially equivalent" devices under the MDA where not sufficiently specific have preemptive effect. Thus, the narrow holding of *Lohr* is that the MDA preempts state law requirements only where they add to or differ from specific federal requirements applicable to a particular device or class of devices.

(f) In deciding to accord "substantial weight" to the FDA's interpretation of the MDA's preemptive scope, the plurality was guided by its understanding of "the structure and purpose" of the MDA as a whole, and significantly, by implied, rather than express preemption principles. For instance, Justice Stevens explains the plurality's reliance on the FDA's interpretive regulations as follows:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 62, 67 (1941), and, therefore, whether it should be preempted.

Id. at 2255 (Stevens, J.).

Of course, the question whether state law "stands as an obstacle to the accomplishment and purpose" of federal law has long been viewed as a question of implied preemption, and *Hines* is among the Court's leading implied preemption decisions. Justice Stevens' subsequent observation that "it is impossible to ignore [the MDA's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest" similarly invokes implied preemption concepts. *See id.* at 2257. Notably,

Justice Stevens' opinion closes with an invitation to undertake an implied preemption analysis in future cases involving questions of preemption under the MDA. *Id.* at 2259.

In his concurring opinion, Justice Breyer likewise introduces implied preemption principles to support his conclusion. Specifically, Justice Breyer discusses "ordinary principles of 'conflict' and 'field' preemption" and states that "[i]t makes sense, in the absence of any indication of a contrary congressional (or agency) intent, to read the [MDA and its related regulations] in light of these basic preemption principles." *Id.* at 2261 (Breyer, J., concurring in part and concurring in the judgment).

Given the remarkable number of references to implied preemption principles in a case involving an express preemption provision, it is perhaps not surprising that Justice Stevens' analysis starts off citing *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88 (1992), a decision in which a majority of the Court could not agree whether the federal law at issue impliedly or expressly preempted certain regulations arising under state law. *Lohr*, 115 S. Ct. at 2250, 2251 (citing and quoting *Gade*). In view of the ambiguity which the plurality found in the express preemption language of the MDA, however, and in view of the considerable effort devoted to discussing the purpose and goals of Congress when it enacted the MDA, it is also not surprising that the plurality turned to implied preemption principles to inform, if not to justify, its decision.

Respondents submit that this latter observation holds the key to understanding the *Lohr* Court's decision. While the narrow holding described above adequately explains the result in *Lohr*, a complete understanding of the Court's decision must look to the rationale underlying the plurality's conclusion. *Lohr* teaches that it may sometimes be difficult to apply the "plain language" of a preemption provision in a way that is consistent with the greater goals Congress had in mind when it enacted the federal statute. Accordingly, unless Congress works with absolute precision, courts undertaking a preemption analysis must bear in mind the purpose and goals of the

federal statute at issue and determine, ultimately, whether enforcement of state law would interfere with the fulfillment of that purpose and the accomplishment of those goals.

B. *Martin v. Telectronics*

Far from conflicting with the teaching of *Lohr*, the United States Sixth Circuit Court of Appeals thoughtfully and faithfully worked through the analysis suggested by this Court. The court began by reciting the MDA's express preemption provision, and, after reviewing this Court's *Lohr* decision, undertook an analysis of the purpose and structure of the MDA as it pertains to the investigational device at issue here. *See Martin*, 105 F.3d at 1093-97.

Initially, the court observed that the purpose of the investigational device exemption is "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use." *Id.* at 1095. The court then reviewed the "complex and comprehensive regulations" applicable to investigational devices, *id.* at 1095-96, and noted that the FDA must be satisfied that "the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained" before it will grant an exemption for a proposed investigation. *Id.* at 1096.

Having established this background, the court turned to a careful comparison between the claims raised by Petitioners below and the federal regulations governing the investigational device at issue. With respect to Petitioners' manufacturing defect claim, the court first determined that there were federal manufacturing regulations "specific to investigational devices." *Id.* at 1098. Without more, this conclusion would have been enough to trigger preemption under the narrow holding of *Lohr* described above. The court expressed concern, however, because it was "questionable" whether the state statute giving rise to Petitioners' claim was developed "with respect to" the device or was merely one of general applicability and therefore did not impose the type of requirement Congress intended for the MDA to preempt. *Id.* at

1099. Looking to implied preemption principles, however, the court concluded that enforcement of Petitioners' manufacturing defect claim "would thwart the goals of the IDE exemption 'to encourage . . . the discovery and development of useful devices intended for human use." *Id.* Accordingly, the court held the manufacturing defect claim preempted. *Id.*

With respect to Petitioners' design defect claim, the court noted that Ohio law provides for a risk/benefit standard or a consumer expectation standard. *Id.* (quoting Ohio Rev. Code § 2307.75). Recalling that the FDA conducts its own device-specific risk benefit analysis prior to granting any investigational device exemption, the court concluded that Ohio law would impose a different requirement insofar as a jury could conclude that the risks of the investigation outweighed its benefits — in contradiction to the FDA's prior determination — and an additional requirement insofar as Ohio law was allowed to superimpose a consumer expectation test on the risk/benefit test required under the MDA. *Id.* Moreover, the court concluded that the enforcement of either standard would "impede the implementation and enforcement" of the applicable provisions of the MDA. *Id.* For all of these reasons, the court found Petitioners' design defect claim preempted.

Petitioners' inadequate warning claims were likewise preempted because of the specific federal provisions governing warning labels and informed consent forms which must be used in conjunction with IDE devices, and as well because enforcement of the state law claim "would impede Congress' intent in enacting the investigational device exemption." *Id.* at 1100. Petitioners' express representation claim was held preempted on the same grounds. *Id.* at 1100-01. Significantly, the court noted that Petitioners had not claimed that Respondents failed to comply with requirements applicable to the device under the MDA's investigational device provisions. *Id.* at 1101.[1]

As can be seen, the *Martin* court conducted a thorough analysis

1. Petitioners' remaining claims, supplier liability and loss of consortium, presented only minor variations on the more substantive claims discussed above. Accordingly, the court did not devote substantial effort to their analysis. *See id.* at 1101.

to ascertain the intent of Congress' in enacting the investigational device provisions of the MDA, and, on a claim by claim basis, determined whether Petitioners' state law causes of action were consistent with, or stood as an obstacle to the accomplishment of that intent. The *Martin* court's approach, and its reasoning, are entirely consistent with this Court's decision in *Lohr*. That the results are different can be readily explained by the different federal regulations governing the respective devices in the two cases.

As noted previously, the federal regulations governing the "substantially equivalent" device at issue in *Lohr* were intended as a stop-gap measure to maintain the status quo until the FDA could implement the substantive provisions of the MDA. And, as this Court observed, the "substantial equivalence" review process does not carry with it the FDA imprimatur of safety and efficacy. Accordingly, the statutory and regulatory provisions applicable to the device in *Lohr* do little if anything to promote the first stated goal of Congress when it enacted the MDA — enhancing public health and safety.[2]

Similarly, almost by definition, the regulations applicable to the *Lohr* device do nothing to promote the second stated goal of the MDA — encouraging innovation. Obviously, regulations which permit pre-1976 medical devices and their post-1976 substantial equivalents to remain on the market do not foster the development of anything new

2. In 1990, Congress amended the MDA to include more stringent safety and effectiveness requirements for manufacturers of "substantially equivalent" devices. *See* 104 Stat. 4515, 4517, 4523, 4528 (1990); *see also* 21 C.F.R. § 807.87(i) (safety and effectiveness regs for post-1990 substantially equivalent devices). These amendments simply codified what had been the past practice of the FDA for at least some substantially equivalent devices. *See* S. Rep. No. 513, 101st Cong., 2d Sess. 28 (1990). In certain cases, for instance, the FDA requires safety and effectiveness data generated in an IDE investigation prior to permitting even a substantially equivalent device to enter the market. *See* 21 C.F.R. §§ 807.92(b)(2) (referring to data from clinical studies included in a § 510(k) submission). The device at issue in *Lohr* was authorized for distribution in 1982, well in advance of the 1990 amendments. *Lohr*, 116 S. Ct. at 2248. The *Lohr* Court did not discuss and apparently had no reason to believe that the device at issue had been subjected to the higher level of safety and effectiveness review contemplated by the amended statute.

in medical device technology. In fact, the substantial equivalence process may actually discourage innovation: rather than developing new devices which must undergo the closely scrutinized IDE process and the exhaustive PMA process, manufacturers may actually have an incentive to rely on old technology insofar as it allows them to reach the market more quickly through the less stringent substantial equivalence regulations. *See Lohr*, 116 S. Ct. at 2248 ("Medtronic took advantage of § 510(k)'s expedited process in October of 1982 when it notified FDA that it intended to market its Model 4011 pacemaker lead as a device that was 'substantially equivalent' to devices already on the market.").

It is not surprising, then, that the *Lohr* Court did not find the claims at issue in that case to have been preempted by the MDA. As the plurality logically observed, by including the substantial equivalence provisions in the MDA

> Congress intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976. There is no suggestion in either the statutory scheme or the legislative history that the [substantial equivalence] exemption process was intended to do anything other than to *maintain the status quo*. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design. Given this background behind the "substantial equivalence" exemption, the fact that "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case, and the presumption against pre-emption, the Court of Appeals properly concluded that the "substantial equivalence" provision did not pre-empt the Lohrs' design claims.

Lohr, 116 S. Ct. at 2255 (citations omitted) (emphasis added).

By contrast to the statutes and regulations at issue in *Lohr*, the provisions of the MDA applicable to the investigational device at issue here were clearly intended to promote the twin aims of Congress — safety and innovation — and *to change the status quo* in both regards. As this Court noted, the MDA "certainly reflects" Congressional intent to promote innovation in medical device technology. *Lohr*, 116 S. Ct. at 2253 & n.12. In fact, the investigational device exemption appears to be the exclusive vehicle chosen by Congress to promote this goal.

Moreover, the IDE provisions of the MDA allow limited distribution of new devices for the purpose of clinical evaluation and data gathering necessary to determine whether the device is safe and effective. *See id.*; *see also* 21 C.F.R. § 812.1(a). To the extent these provisions allow the collection of clinical data necessary to the PMA review and approval process, they support Congress' goal of enhancing public health and safety in addition to encouraging innovation. *See, e.g.*, 21 C.F.R. § 814.20(b)(3)(v)(B) (discussing inclusion of IDE clinical data in PMA application). It must also be noted that all of the statutory and regulatory provisions governing IDE devices were specifically designed to balance "the protection of public health and safety" with the need to encourage "the discovery and development of useful devices." 21 U.S.C. § 360j(g)(1); 21 C.F.R. § 812.1(a). Thus, perhaps more so than any other provision of the MDA, the IDE requirements were intended to promote both stated goals of Congress.

The IDE regulations differ from those applicable to "substantially equivalent" devices in other ways as well. Unlike the "general federal requirements" discussed in *Lohr*, the MDA's statutory and regulatory structure reveals that the requirements imposed on manufacturers of investigational devices are truly device-specific. For example, the MDA's PMA requirements are the default for all Class III devices. 21 U.S.C. § 360e(a). The IDE regulations do not come into play unless and until a manufacturer submits an IDE application and an investigational plan for a specific device. 21 U.S.C. § 360j(g)(2) (directing the FDA to promulgate regulations whereby a Class III device "may *upon application* be granted an exemption" from PMA

requirements) (emphasis added); *id.* § 360j(g)(2)(B)(ii) (defining requirements applicable to "the person applying for an exemption for *a device*) (emphasis added). The entire content of the application is particular to that device, *see* 21 C.F.R. § 812.20, as is the proposed investigational plan, *see id.* § 820.25.

FDA review and action on an IDE application is similarly device-specific. *See id.* § 812.30(b). For instance, the FDA requires information regarding "the methods, facilities, and controls used for the manufacture . . . of *the device*, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of *the device*," but exempts the manufacturer from the Good Manufacturing Practice requirements which would otherwise apply. 21 C.F.R. § 812.30(b)(3) (requiring manufacturing process information) (emphasis added); § 812.1(a) (exempting investigational device manufacturers from GMP requirements). Perhaps most significantly, the grant of an investigational device exemption for a particular device comes only through a specific FDA order. *Id.* § 812.30(a)(2). This process of application, review and approval-by-order leaves little room for doubt that the requirements imposed on a particular investigational device under the MDA are specific indeed.

Finally, and of significance to the *Martin* court, the FDA conducts a "risk/benefits" analysis for each investigational device application and grants an exemption only if "the risks to the subjects" are "outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained" from the particular investigation under review. *Martin*, 105 F.3d at 1096, 1099; *see also* 21 C.F.R. § 812.30(b)(4); 21 C.F.R. § 56.111 (requiring similar risk/benefit analysis to be undertaken by the Institutional Review Board responsible for overseeing the investigation). This type of FDA oversight is apparently significant to this Court as well; discussing the federal regulations applicable to the "substantially equivalent" device in *Lohr*, the Court observed that:

> The generality of [the substantial equivalence]

> requirements make this quite unlike a case in which the Federal Government *has weighed the competing interests* relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved *in a particular case or set of cases*, and implemented that conclusion via *a specific mandate on manufacturers* or producers.

Lohr, 116 S. Ct. at 2258 (emphasis added).

In view of the foregoing, Respondents submit that the Sixth Circuit Court of Appeals has faithfully adhered to this Court's teaching in *Lohr*. Further, Respondents submit that the reasoning of *Lohr*, when applied to the particular facts and the particular state and federal laws at issue in this case, supports the different result reached by the Sixth Circuit. There is no conflict and no inconsistency in the application of law, and the decision of the Sixth Circuit should stand.

C. Conflict with Other Decisions

Petitioners also suggest that the Sixth Circuit's decision conflicts with decisions from other federal appellate courts. A brief discussion of each of the cases cited by Petitioners reveals the fallacy of this argument.

1. *Oja v. Howmedica*

This Tenth Circuit decision is easily distinguishable on several grounds. First, the device at issue — a prosthetic hip replacement — was being marketed under § 510(k) of the MDA at the time of plaintiff's implant surgery. *Oja v. Howmedica, Inc.*, 111 F.3d 782, 1997 U.S. App. LEXIS 7175 (10th Cir. 1997). At least that was true for the version of the product used with bone cement. *Id.*, 1997 U.S. App. LEXIS at *10. At some point, Howmedica submitted an IDE application to conduct a clinical study of the device without bone cement. *Id.* This application was still pending, however, when the plaintiff's physician

decided to implant the device without using cement. *Id.* at *10 & n.2. Thus, it is unclear whether *any* federal requirements were applicable to the device at issue. Ultimately, the FDA classified the device — used with or without bone cement — as Class II. *Id.* at *11-12. Without ever stating precisely what federal requirements may have been applicable to the device, the Tenth Circuit noted that the device was not subject to IDE regulations, and thus distinguishable from the device at issue in *Martin* and in *Becker v. Richards Medical Co.*, 937 F. Supp. 181 (N.D.N.Y. 1996). *See id.* at *10 n. 2.

2. *Duvall v. Bristol-Myers-Squibb Co.*

Like *Lohr*, but unlike the instant case, *Duvall* involved a "substantially equivalent" device authorized for market distribution pursuant to § 510(k) of the MDA. *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 328 (4th Cir. 1996). Petitioners point out that prior to achieving "substantially equivalent" status, the device had undergone clinical testing pursuant to an investigational device exemption. The Fourth Circuit's opinion is unequivocal, however, in its treatment of the device as "substantially equivalent" rather than investigational. *Id.* at 328. There is no suggestion in the court's opinion that the plaintiff took part in the investigation or was otherwise afforded the protections, such as the requisite informed consent, typically associated with investigational devices.

3. *Chambers v. Osteonics Corp.*

Petitioners partially mischaracterize this decision as one in which a "negligent manufacturing claim" against the manufacturer of an investigational hip prosthesis was not preempted. In fact, the Seventh Circuit held that all of the plaintiff's claims *except* negligent manufacturing were preempted by the MDA. *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1997 U.S. App. LEXIS 6301 (7th Cir. 1997). Moreover, the single claim that survived preemption did so only because the plaintiff's claim was "expressly limited to Osteonics' failure to comply with the standards and procedures set out by the FDA in the IDE process." *Id.*, 1997 U.S. App. LEXIS 6301 at *16. The Sixth

Circuit in *Martin* explicitly agreed with this position, noting that "a claim that [Respondents] did not comply with MDA regulations governing its device would not be preempted. . . ." *Martin*, 105 F.3d at 1101. Unfortunately for Petitioners, the Sixth Circuit also noted that Petitioners "failed to allege below that [Respondents] did not comply with MDA regulations governing devices approved under the IDE. Thus, any remedy available to [Petitioners] under a failure to comply with federal regulations theory has been waived." *Id.*

4. *Papike v. Tambrands, Inc.*

As Petitioners concede, this case involves a Class II rather than a Class III device, and has nothing whatever to do with the regulations governing investigational device exemptions. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 1997 U.S. App. LEXIS 2870 (9th Cir. 1997). The decision thus has little if any bearing on the question of preemption in the context of a Class III investigational device such as the one at issue here. Perhaps the most significant aspect of *Papike* lies in its acknowledgment that the conclusions drawn by the same court in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) — that common law claims against the manufacturer of a Class III PMA device were not preempted — "cannot survive in light of the concurring and dissenting opinions" in this Court's *Lohr* decision. *Papike*, 1997 U.S. App. LEXIS at *11-12.

5. *Reeves v. Acromed Corp.*

This case involves a "substantially equivalent" device and, not surprisingly, replicates the reasoning and result of *Lohr*. *See Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. 1997). As such, it adds little to the discussion of preemption under the MDA with respect to investigational devices.

6. *Wilson v. Bradlees of New England, Inc.*

Petitioners' reference to this decision is somewhat bewildering in that it involves children's clothing rather than medical devices, and involves a completely different federal statute with an express

preemption provision that speaks of "standard[s]" and "regulation[s]" rather than the more general "any requirement" language in the MDA. *See Wilson v. Bradlees of New England, Inc.*, 96 F.3d 522 (1st Cir. 1996). As noted in Section III of this brief, however, Petitioners' citation to *Wilson* as a plea for additional guidance on the question of federal preemption may be one worthy of this Court's consideration.

II. THIS CASE DOES NOT PRESENT A CONSTITUTIONAL ISSUE THAT SHOULD BE DECIDED BY THIS COURT [RESTATED].

The Constitution establishes our federal government as a government of limited powers, and carefully defines the areas in which federal authority may appropriately be exercised. Within those carefully defined areas, however, the "Supremacy Clause" of the Constitution provides that federal law "shall be the supreme Law of the Land . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. This Court has held again and again that Congress has the authority under the Supremacy Clause to preempt state law, including state common law claims. *E.g., American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992); *Chicago & N.W. Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981); *Texas & Pacific Rwy. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426 (1907).

Notwithstanding this precedent, Petitioners submit that the Seventh Amendment constrains the supremacy of federal law to the extent it impacts upon any state common law claims that existed as of December 15, 1791, the date the Seventh Amendment was ratified. In other words, Petitioners assert that Congress is powerless to preempt traditional state common law claims even when Congress is appropriately exercising the authority given it under Article I of the Constitution.[3]

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3. Petitioners have not suggested that federal regulation of medical devices, as embodied in the Medical Device Amendments to the Food, Drug and Cosmetic Act, is an inappropriate exercise of Congressional power or that such regulation exceeds the limits established in Article I.

This argument misapprehends the language, the scope and the very purpose of the Seventh Amendment and thus does not raise a Constitutional issue worthy of review by this Court.

In its entirety, the Seventh Amendment provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of common law.

As the language of the amendment itself makes plain, the right being protected — the right to a jury trial in civil lawsuits —presupposes the existence of a "Suit[] at common law." In this case, there is no "Suit[] at common law" because Petitioners' common law claims have been expressly preempted, a priori, by the Medical Device Amendments to the federal Food, Drug and Cosmetic Act. Where there is no "Suit[] at common law" due to the operation of the Supremacy Clause, the right of trial by jury simply is not implicated because there is no underlying lawsuit to which the right can attach.

The Sixth Circuit Court of Appeals correctly stated this principle, observing that

> [n]othing in its text or history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. . . . Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[] at common law" and the Seventh Amendment's guarantees are not implicated.

Martin v. Telectronics Pacing Systems, Inc., 70 F.3d 39, 42 (6th Cir. 1995). The court reiterated this view on remand, stating that "We see

no reason to depart from our previous holding on this issue." *Martin*, 105 F.3d 1090, 1101 (6th Cir. 1997). This same reasoning is reflected in numerous court decisions holding that there is no constitutionally protected right to bring a tort claim.[4] The reasoning articulated by the Sixth Circuit Court of Appeals also comports with numerous analogous decisions involving the right of trial by jury. For example, in *Etalook v. Exxon Pipeline Co.*, 831 F.2d 1440 (9th Cir. 1987), the court addressed the question whether granting summary judgment infringes on a litigant's right to a jury trial. The court concluded that "no right of jury trial exists unless there is a genuine issue of material fact suitable for a jury to resolve." *Id.* at 1447. Similarly, in *3 Penny Theater Corp. v. Plitt Theatres, Inc.*, 812 F.2d 337 (7th Cir. 1987), the court concluded that dismissal of a plaintiff's claims with prejudice for failure to prosecute pursuant to Fed. R. Civ. P. 41(b) did not violate the plaintiff's right to a trial by jury. And in *Sullivan v. United States*, 788 F.2d 813 (1st Cir. 1986), the court found no violation of the plaintiff's right to a jury trial based on the trial court's dismissal for failure to state a claim upon which relief could be granted.

In each of the above-cited decisions, the right to trial by jury never arose because plaintiff's claims were determined to be unsupportable *as a matter of law*. Given the time-honored role of juries as finders of *fact*, there is no legal or logical reason for jury involvement in a case that can be and is decided on purely legal grounds. It necessarily follows that claims which can be resolved as a matter of law simply do not implicate the Seventh Amendment guarantees. This case is no different. Petitioners' claims were held to be preempted by the express preemption provisions of the MDA as a matter of law. As a result, the right to trial by jury never becomes an issue.

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4. *See, e.g., Cooperativa de Ahorro y Credito Aguada v. Kidder, Peabody & Co.*, 993 F.2d 269 (1st Cir. 1993) (no protectable right in a tort claim "until a final, unreviewable judgment has been obtained") (citations omitted); *Hammond v. United States*, 786 F.2d 8 (1st Cir. 1988) (same); *Donaldson v. Volkswagenswerk Aktiengesellschaft*, 631 F. Supp. 1144 (S.D. Fla. 1986) (no constitutionally protected right in a tort claim), *aff'd sub nom.*, 835 F.2d 1369 (11th Cir.), *cert. denied sub nom.*, 488 U.S. 822 (1988).

Petitioners' argument to the contrary turns this straightforward calculus on its head. According to Petitioners, it is not the right to jury trial that is preserved by the Seventh Amendment, but the underlying common law claim itself: "Congress cannot pass a law that abrogates an individual's right to a trial by jury where the cause of action existed prior to 1791; and the Seventh Amendment as an amendment takes precedence over the Supremacy Clause." Stretched to its extreme, this argument would make it impossible for a court to ever dispose of a lawsuit on purely legal grounds without running afoul of the Seventh Amendment. Similarly, this argument would make it impossible for Congress to exercise its power under Article I and the Supremacy Clause if, in so doing, it undermined any common law theory of recovery which may have existed in the late eighteenth century.

Indeed, careful consideration of Petitioners' argument reveals inherent contradictions and fatal flaws in logic. For instance, acceptance of Petitioners' argument would, at some fundamental level, result in the wholesale destruction of the common law paradigm. Instead of an evolving body of law representing the culmination of legal principles and societal wisdom gleaned through the ages, Petitioners' vision of the common law is one that is fixed in time. According to Petitioners, the Seventh Amendment essentially codified the common law as it existed in 1791 and admits of no alterations to that codification. Accepting Petitioners' argument would be tantamount to accepting blanket prohibition of the growth, change and adaptation that are the hallmarks of our common law system, and would effectively consign the contributions of such legal lights as Holmes, Cardozo and Llewellyn to the scrap heap. It is doubtful at best whether the Framers could have intended such a result while simultaneously embracing the common law heritage of their English forebears.

That this Court has traditionally taken an "historical approach" in its Seventh Amendment jurisprudence does not save Petitioners' argument. This Court has long interpreted the Seventh Amendment as reaching only those cases cognizable in law, as opposed to those historically brought in equity or admiralty. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989). To make these distinctions in a manner

consistent with the Framers' intent, this Court has found it is necessary to conduct an historical analysis of the differences among law, equity and admiralty as they existed in 1791. *E.g., Tull v. United States,* 481 U.S. 412 (1987). It is a leap of illogic, however, for Petitioners to draw from this analytical approach the conclusion that the Framers intended the Seventh Amendment to petrify the common law itself as it existed in eighteenth century America.

Petitioners candidly admit there is no authority whatsoever for the proposition that "the Seventh Amendment preserve[s] a cause of action in and of itself." Pet. at 11. Perhaps as a result of this dearth of supporting authority, Petitioners attempt to supplement their Seventh Amendment argument with reference to the Ninth and Tenth Amendments, apparently for the proposition that the Constitution does not grant Congress the authority to preempt state common law claims. No reference was made to the Ninth and Tenth Amendments at trial as potential grounds for invalidating the MDA. Accordingly, these arguments should not now be considered for the first time on appeal.

III. RESPONDENTS ACKNOWLEDGE POTENTIAL CONFLICT BETWEEN THE SIXTH CIRCUIT'S DECISION AND THE DECISION OF THE MISSOURI SUPREME COURT IN *CONNELLY V. IOLAB*, AND RESPECTFULLY SUBMIT THAT THIS CASE PROVIDES THE MORE APPROPRIATE VEHICLE FOR ANY CLARIFICATION BY THIS COURT OF ITS PRIOR DECISION REGARDING THE SCOPE OF PREEMPTION UNDER THE MDA.

Somewhat surprisingly, Petitioners failed to mention the Missouri Supreme Court's decision in *Connelly v. Iolab Corp.*, 927 S.W. 2d 848 (Mo. 1996), *pet'n for cert. pending sub nom., Iolab Corp. v. Hunter*, Docket No. 96-1126, which arguably is one case that does conflict with the Sixth Circuit's *Martin* opinion.

Like this case, *Iolab* involves state law claims against the manufacturer of an investigational device. *Iolab*, 927 S.W. 2d at 850. And like the Sixth Circuit in this case, the Missouri Supreme Court

incorporated implied preemption principles into its analysis. *See id.* at 853-855. There the similarities end. The Missouri court limited its view of preemption under the MDA to those situations where it was impossible to comply with both state and federal law. *Id.* at 853 ("If any basis of common law liability asserted by plaintiffs conflicts with a federal regulation in such a way as to make performance of both impossible, the state common law claim is preempted."). Having adopted this restrictive view, and finding that it was not impossible for the manufacturer to satisfy both the federal IDE requirements and such design, manufacturing, labeling and warning requirements as might be imposed under Missouri common law, the court concluded that none of the plaintiff's claims were preempted.

Iolab petitioned this Court for certiorari review of the Missouri court's decision. Recently, on April 21, 1997, this Court issued an order inviting the Solicitor General to submit a brief on behalf of the United States — and more particularly, the FDA — setting forth the FDA's position on MDA preemption with respect to investigational devices. *Iolab Corp. v. Hunter*, 117 S. Ct. 1466 (1997). As a result of this order, and in view of the persistent confusion among the courts regarding the scope of preemption under the MDA, Respondents believe the Court may be inclined to take up the issue once again, this time in the context of investigational devices.

Should the Court be so inclined, Respondents respectfully submit that the instant case, rather than the *Iolab* case, provides the best opportunity for this Court to explicate its prior decision. In support of this contention, Respondents offer the following observations:

(a) *Martin* potentially reaches a broader range of medical devices, and accordingly a broader range of claims which may be subject to preemption under the MDA. Specifically, the federal regulations at issue in *Martin* pertain to all investigational devices, whereas intraocular lenses, such as the device at issue in *Iolab*, are governed by their own separate set of regulations. *Compare* 21 C.F.R. Part 812 (regulations governing investigational devices generally) *with* 21 C.F.R. Part 813 (regulations governing investigational intraocular lenses). In the event

the Court were to conclude, for instance, that the claims in *Iolab* should be preempted because the federal regulations in question are sufficiently specific, it would remain uncertain whether claims against manufacturers of all other investigational devices are similarly preempted. Moreover, Respondents submit that the Sixth Circuit's careful analysis of the goals underlying the MDA might provide an appropriate platform for guidance on the question of preemption in the context of PMA devices as well. No such opportunity is afforded by the Missouri court's opinion which, quite simply, does not discuss the effect that its decision, and the enforcement of state common law claims, will have on "the accomplishment and execution of the full purposes and objectives of Congress" when it enacted the MDA.

(b) *Martin* provides this Court with an opportunity to put the "common law vs. positive enactments" debate to rest. Specifically, *Martin* involved claims arising under Ohio statutory law because Ohio, like several other states, has chosen to codify its product liability common law. *Martin*, 105 F.3d at 1092; *cf. Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1997 U.S. App. LEXIS 6301 at *16 (7th Cir. 1997) (distinguishing *Martin* on the ground that the claims at issue there arose from Ohio statutory law rather than common law). The nature and the impact of the claims in *Martin* are virtually the same as analogous claims arising under the common law of other jurisdictions. However, the fact that they are premised on "positive enactments of state law" rather than common law will allow this Court to focus narrowly on the type of state-law requirements that should be preempted, regardless of their source.

(c) Although it should not be necessary to the Court's determination, Petitioners' argument regarding the 510(k) status of two component parts of the investigational device in *Martin* raises a recurring question that should be resolved. As noted in both the *Oja* and *Duvall* decisions, different medical devices over the course of their product life cycle may be governed at different times by "substantially equivalent" regulations, IDE regulations, or PMA regulations. This is simply a reality inherent in the structure and the practical application of the MDA. Insofar as this regulatory evolution presents problems for

courts and litigants faced with preemption questions arising under the MDA, *Martin* gives this Court an opportunity to resolve them.

(d) Finally, Respondents submit that the Sixth Circuit's *Martin* decision is the better reasoned and thus provides the better "template" for a clarification decision from this Court. As noted previously, the Sixth Circuit faithfully adhered to the principles set forth in *Lohr*, beginning with the language of the statute, followed by a reasoned assessment of the structure and purpose of the statute, and turning to fundamental principles of conflict preemption to resolve questions left unanswered by the MDA's express preemption language. By contrast, the Missouri court erroneously described the device at issue in *Lohr* as a hearing aid, *see Iolab*, 927 S.W. 2d at 852, treated as a holding the "common law vs. positive enactment" distinction which did not command a majority of the Court, *see id.* at 853 ("Under the plurality opinion, there are no positive enactments of state statutes or regulations at issue here and thus no preemption."), and, without explanation or justification, limited the application of implied preemption principles to situations in which compliance with both state and federal requirements was "impossible." *See id.*

For all the foregoing reasons, Respondents respectfully suggest that the Court give favorable consideration to this case, rather than the *Iolab* case, in the event it is inclined to revisit the question of preemption under the MDA in the context of investigational devices.

CONCLUSION

For the foregoing reasons, Respondents pray that this Court deny the Petition for Writ of Certiorari sought by Petitioners, thus maintaining intact the considered opinion of the Sixth Circuit Court of Appeals. However, should this Court be inclined to revisit the question of federal preemption under the MDA in the context of investigational devices, Respondents respectfully submit that it would be preferable for the Court to review the Sixth Circuit's decision in *Martin* rather than the decision of the Missouri Supreme Court in *Connelly v. Iolab.*

Respectfully submitted,

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